UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-Q

(Mark One)

x QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2012

OR

o TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission File Number: 0-30319

THERAVANCE, INC.
(Exact Name of Registrant as Specified in its Charter)

Delaware	**94-3265960**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)

901 Gateway Boulevard
South San Francisco, CA 94080
(Address of Principal Executive Offices including Zip Code)

(650) 808-6000
(Registrant's Telephone Number, Including Area Code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No o

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definitions of "large accelerated filer," "accelerated filer," and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer x	Accelerated filer o
Non-accelerated filer o (Do not check if a smaller reporting company)	Smaller reporting company o

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes o No x

The number of shares of registrant's common stock outstanding on October 24, 2012 was 97,857,208.

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PART I — FINANCIAL INFORMATION

Item 1. Financial Statements

THERAVANCE, INC.
CONDENSED CONSOLIDATED BALANCE SHEETS
(In thousands, except per share data)

	September 30, 2012 (Unaudited)	December 31, 2011 *
Assets		
Current assets:		
Cash and cash equivalents	$ 112,235	$ 44,778
Short-term investments	161,209	196,137
Receivable from related party	71	223
Note receivable, current	100	100
Prepaid and other current assets	3,772	3,525
Inventory	5,148	—
Total current assets	282,535	244,763
Long-term marketable securities	88,962	—
Restricted cash	833	893
Property and equipment, net	9,579	10,372
Notes receivable, non-current	140	240
Other assets, non-current	1,894	2,514
Total assets	$ 383,943	$ 258,782
Liabilities and stockholders' equity (net capital deficiency)		
Current liabilities:		
Accounts payable	$ 4,757	$ 5,813
Accrued personnel-related expenses	7,714	9,643
Accrued clinical and development expenses	6,761	6,956
Accrued interest on convertible subordinated notes	1,078	2,372
Other accrued liabilities	1,835	1,946
Note payable and capital lease	—	69
Deferred revenue, current	4,945	18,697
Total current liabilities	27,090	45,496
Convertible subordinated notes	172,500	172,500
Deferred rent	5,275	5,821
Deferred revenue, non-current	5,790	122,017
Commitments and contingencies (Notes 3 and 7)		
Stockholders' equity (net capital deficiency):		
Common stock, $0.01 par value; authorized: 200,000 shares; outstanding: 97,854 at September 30, 2012 and 85,543 at December 31, 2011	979	855
Additional paid-in capital	1,475,371	1,228,037
Accumulated other comprehensive income	116	16

Accumulated deficit	(1,303,178)	(1,315,960)
Total stockholders' equity (net capital deficiency)	173,288	(87,052)
Total liabilities and stockholders' equity (net capital deficiency)	$ 383,943	$ 258,782

* Condensed consolidated balance sheet at December 31, 2011 has been derived from audited consolidated financial statements.

See accompanying notes to condensed consolidated financial statements.

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THERAVANCE, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share data)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Revenue (including amounts from a related party: three months —2012-$1,430; 2011-$2,380; nine months—2012-$4,291; 2011-$7,294)	$ 1,430	$ 6,431	$ 129,960	$ 19,150
Operating expenses:				
Research and development	27,026	27,837	89,778	71,099
General and administrative	7,754	7,796	23,201	22,213
Total operating expenses	34,780	35,633	112,979	93,312
Income (loss) from operations	(33,350)	(29,202)	16,981	(74,162)
Interest income	158	81	304	344
Interest expense	(1,500)	(1,505)	(4,503)	(4,519)
Net income (loss)	$ (34,692)	$ (30,626)	$ 12,782	$ (78,337)
Net income (loss) per share:				
Basic net income (loss) per share	$ (0.37)	$ (0.37)	$ 0.14	$ (0.96)
Diluted net income (loss) per share	$ (0.37)	$ (0.37)	$ 0.18	$ (0.96)
Shares used to compute basic earnings per share	95,027	82,490	89,271	81,777
Shares used to compute diluted earnings per share	95,027	82,490	98,381	81,777

See accompanying notes to condensed consolidated financial statements.

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THERAVANCE, INC.
CONDENSED CONSOLIDATED STATEMENTS OF COMPREHENSIVE INCOME (LOSS)
(In thousands)
(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Net income (loss)	$ (34,692)	$ (30,626)	$ 12,782	$ (78,337)
Other comprehensive income (loss):				
Net unrealized gain (loss) on available-for-sale securities, net of tax	225	(17)	100	24
Comprehensive income (loss)	$ (34,467)	$ (30,643)	$ 12,882	$ (78,313)

See accompanying notes to condensed consolidated financial statements.

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THERAVANCE, INC.
CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS
(In thousands)
(Unaudited)

	Nine Months Ended September 30,	
	2012	2011
Cash flows from operating activities		
Net income (loss)	$ 12,782	$ (78,337)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	5,462	5,459
Gain on sales of available-for-sale securities	(8)	—
Stock-based compensation	18,044	18,706
Forgiveness of notes receivable	—	16
Changes in operating assets and liabilities:		
Receivables	152	113
Prepaid expenses and other current assets	(247)	1,983
Inventory	(4,567)	—
Accounts payable	(452)	1,446
Accrued personnel-related expenses, accrued interest on convertible subordinated notes and other current liabilities	(3,902)	(679)
Deferred rent	(546)	2,336
Deferred revenue	(129,979)	(14,025)
Net cash used in operating activities	(103,261)	(62,982)
Cash flows from investing activities		
Purchases of property and equipment	(2,329)	(2,723)
Purchases of short-term investments and marketable securities	(276,425)	(231,284)
Sales of short-term investments and marketable securities	181,495	8,750
Maturities of short-term investments and marketable securities	38,670	164,401
Release of restricted cash	60	—
Issuances of notes receivable	(140)	(140)
Payments received on notes receivable	240	630
Net cash used in investing activities	(58,429)	(60,366)
Cash flows from financing activities		
Payments on note payable and capital lease	(69)	(166)
Proceeds from issuances of common stock, net	229,216	22,917
Net cash provided by financing activities	229,147	22,751
Net increase (decrease) in cash and cash equivalents	67,457	(100,597)
Cash and cash equivalents at beginning of period	44,778	163,333
Cash and cash equivalents at end of period	$ 112,235	$ 62,736

See accompanying notes to condensed consolidated financial statements.

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Theravance, Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

1. Description of Operations and Summary of Significant Accounting Policies

Description of Operations

Theravance, Inc. (the Company or Theravance) is a biopharmaceutical company with a pipeline of internally discovered product candidates and strategic collaborations with pharmaceutical companies. Theravance is focused on the discovery, development and commercialization of small molecule medicines across a number of therapeutic areas including respiratory disease, bacterial infections, and central nervous system (CNS)/pain.

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements of the Company have been prepared in accordance with U.S. generally accepted accounting principles (GAAP) for interim financial information and the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and notes required by GAAP for complete financial statements. In the opinion of the Company's management, the unaudited condensed consolidated financial statements have been prepared on the same basis as audited consolidated financial statements and include all adjustments, consisting of only normal recurring adjustments, necessary for the fair presentation of the Company's financial position, results of operations, comprehensive income (loss) and cash flows. The interim results are not necessarily indicative of the results of operations to be expected for the year ending December 31, 2012 or any other period.

The accompanying unaudited condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements and notes thereto included in the Company's Annual Report on Form 10-K for the year ended December 31, 2011 filed with the Securities and Exchange Commission (SEC) on February 27, 2012.

Principles of Consolidation

The condensed consolidated financial statements include the accounts of the Company and its wholly owned subsidiaries. All intercompany balances and transactions have been eliminated in consolidation.

Use of Management's Estimates

The preparation of condensed consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the amounts reported in the condensed consolidated financial statements and accompanying notes. Actual results could differ materially from those estimates.

Segment Reporting

The Company has determined that it operates in a single segment which is the discovery (research), development and commercialization of human therapeutics. Revenues are generated primarily from the Company's collaborations with GlaxoSmithKline plc (GSK), located in the United Kingdom, and, through January 6, 2012, Astellas Pharma Inc. (Astellas), located in Japan. All long-lived assets are maintained in the United States.

Marketable Securities

The Company determines the appropriate classification of its marketable securities, which consist of debt securities, at the time of purchase and reevaluates such designation at each balance sheet date. All of the marketable securities are classified as available-for-sale and carried at estimated fair values and reported in either: cash equivalents, short-term investments or long-term marketable securities. Unrealized gains and losses on available-for-sale securities are reported in the condensed consolidated statements of comprehensive income (loss). Interest, amortization of purchase premiums and discounts, and realized gains and losses on sales of marketable securities are included in interest income. The cost of securities sold is based on the specific identification method.

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The Company regularly reviews all of its investments for other-than-temporary declines in fair value. The Company's review includes the consideration of the cause of the impairment, including the creditworthiness of the security issuers, the number of securities in an unrealized loss position, the severity and duration of the unrealized losses, whether the Company has the intent to sell the securities, and whether it is more likely than not that the Company will be required to sell the securities before the recovery of their amortized cost basis. When the Company determines that the decline in fair value of an investment is below the amortized cost basis and the decline is other-than-temporary, the Company reduces the carrying value of the security and records a loss for the amount of such decline.

Inventories

Inventories are stated at the lower of cost or market value. Cost is determined using an average cost basis. Inventories include VIBATIV® active pharmaceutical ingredient and other raw materials of $4.3 million and work-in-process of $0.8 million at September 30, 2012. VIBATIV® is a U.S. Food and Drug Administration (FDA) approved drug. If information becomes available that suggests the inventories may not be realizable, the Company may be required to expense a portion or all of the capitalized inventory costs.

In May 2012, the Company entered into a Technology Transfer and Supply Agreement with Hospira Worldwide, Inc. (Hospira). The Company must obtain regulatory approval for the VIBATIV® drug product that will be manufactured at Hospira's facility before any such product may be sold, and this regulatory approval process could extend through mid-2013.

Research and Development Costs

Research and development costs are expensed in the period that services are rendered or goods are received. Research and development costs consist of salaries and benefits, laboratory supplies and facility costs, as well as fees paid to third parties that conduct certain research and development activities on behalf of the Company, net of certain external research costs reimbursed by GSK and, through 2011, Astellas.

Fair Value of Stock-Based Compensation Awards

The Company uses the Black-Scholes-Merton option pricing model to estimate the fair value of options granted under its equity incentive plans and rights to acquire stock granted under its employee stock purchase plan (ESPP). The Black-Scholes-Merton option valuation model requires the use of assumptions, including the expected term of the award and the expected stock price volatility. The Company used the "simplified" method as described in Staff Accounting Bulletin No. 107 for the expected option term because the usage of its historical exercise data is limited due to post-IPO exercise restrictions. Beginning April 1, 2011, the Company used its historical volatility to estimate expected stock price volatility. Prior to April 1, 2011, the Company used peer company price volatility to estimate expected stock price volatility due to the Company's limited historical common stock price volatility since its initial public offering in 2004.

Restricted Stock Units (RSUs) and Restricted Stock Awards (RSAs) are measured based on the fair market values of the underlying stock on the dates of grant.

Stock-based compensation expense was calculated based on awards ultimately expected to vest and was reduced for estimated forfeitures at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differed from those estimates. The Company's estimated annual forfeiture rates for stock options, RSUs and RSAs were based on its historical forfeiture experience.

The estimated fair value of stock options, RSUs and RSAs is expensed on a straight-line basis over the expected term of the grant and the fair value of performance-contingent RSUs and RSAs is expensed using an accelerated method over the term of the award once the Company determined that it was probable that those performance milestones would be achieved.

Compensation expense for purchases under the ESPP is recognized based on the estimated fair value of the common stock on the date of offering and purchase discount percentage.

The Company has not recognized, and does not expect to recognize in the near future, any tax benefit related to employee stock-based compensation expense as a result of the full valuation allowance on the Company's deferred tax assets including deferred tax assets related to its net operating loss carryforwards.

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Foreign Currency

The Company uses the U.S. dollar as the functional currency for its foreign subsidiary. Monetary and non-monetary assets and liabilities are remeasured into U.S. dollars at the applicable period end exchange rate. Operating expenses are remeasured at average exchange rates in effect during each period, except for those expenses related to non-monetary assets which are remeasured at historical exchange rates. Gains or losses from remeasurement of foreign currency financial statements into U.S. dollars are included in the condensed consolidated statements of operations and were insignificant for all periods presented, as was the effect of exchange rate changes on cash and cash equivalents.

Recently Adopted Accounting Update

On January 1, 2012, the Company adopted Accounting Standards Update (ASU) No. 2011-05, "Presentation of Comprehensive Income," an update to Accounting Standards Codification (ASC) Topic 220, "Comprehensive Income". This update requires that all nonowner changes in stockholders' equity (net capital deficiency) be presented either in a single continuous statement of comprehensive income (loss) or in two separate but consecutive statements. This update was effective for the Company January 1, 2012. The Company elected the two separate but consecutive statements approach.

2. Net Income (Loss) per Share

Basic net income (loss) per share for each period presented was computed by dividing net income (loss) by the weighted-average number of shares of common stock outstanding, less RSAs subject to forfeiture.

For the nine months ended September 30, 2012, diluted net income per share was computed by dividing net income plus interest on dilutive convertible subordinated notes by the weighted-average number of shares of common stock outstanding during the period, less RSAs subject to forfeiture, plus all additional common shares that would have been outstanding assuming dilutive potential common shares had been issued for dilutive convertible notes (see Note 6) and other dilutive securities.

Dilutive potential common shares were calculated based on the "if-converted" method. Under the "if-converted" method, when computing the dilutive effect of convertible notes, net income was adjusted to add back the amount of interest and debt issuance costs recognized in the period and the denominator was adjusted to add back the number of shares that would be issued if the entire obligation was settled in shares.

Dilutive potential common shares also include the dilutive effect of the common stock underlying in-the-money stock options and ESPP shares, and were calculated based on the average share price for each period using the treasury stock method. Under the treasury stock method, the exercise price of an option and the average amount of compensation cost, if any, for future service that the Company has not yet recognized when the option is exercised, are assumed to be used to repurchase shares in the current period. Dilutive potential common shares also reflect the dilutive effect of unvested restricted stock units.

For the three months ended September 30, 2012, and for the three and nine months ended September 30, 2011, diluted net loss per share was identical to basic net loss per share since potential common shares were excluded from the calculation, as their effect was anti-dilutive.

The computations for basic and diluted net income (loss) per share were as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands, except for per share amounts)	2012	2011	2012	2011
Numerator:				
Net income (loss) — basic	$ (34,692)	$ (30,626)	$ 12,782	$ (78,337)
Add: interest and issuance costs related to convertible notes	—	—	4,503	—
Net income (loss) — diluted	$ (34,692)	$ (30,626)	$ 17,285	$ (78,337)
Denominator:				
Weighted-average common shares outstanding	97,590	84,951	91,834	84,238
Less: unvested RSAs	(2,563)	(2,461)	(2,563)	(2,461)
Weighted-average common shares outstanding — basic	95,027	82,490	89,271	81,777
Effect of dilutive equity incentive plans and ESPP	—	—	2,442	—
Effect of dilutive convertible subordinated notes	—	—	6,668	—
Weighted-average common shares outstanding —diluted	95,027	82,490	98,381	81,777

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Anti-Dilutive Securities

Common equivalent shares not included in the computation of diluted net income (loss) per share because their effect was anti-dilutive were as follows:

(in thousands)	Three Months Ended September 30, 2012	Three Months Ended September 30, 2011	Nine Months Ended September 30, 2012	Nine Months Ended September 30, 2011
Shares issuable under Equity Incentive Plans and ESPP	5,098	6,744	2,915	6,205
Shares issuable upon the conversion of convertible subordinated notes	6,668	6,668	—	6,668
Total anti-dilutive securities	11,766	13,412	2,915	12,873

3. Collaboration Arrangements

GSK

LABA collaboration

In November 2002, the Company entered into its long-acting beta$_2$ agonist (LABA) collaboration with GSK to develop and commercialize once-daily LABA products for the treatment of chronic obstructive pulmonary disease (COPD) and asthma. For the treatment of COPD, the collaboration is developing two combination products: Relvar™ or Breo™ (FF/VI) and umeclidinium bromide/vilanterol (UMEC/VI). For the treatment of asthma, the collaboration is developing FF/VI. FF/VI is an investigational once-daily combination medicine consisting of a LABA, vilanterol (VI), and an inhaled corticosteroid (ICS), fluticasone furoate (FF). UMEC/VI is an investigational once-daily combination medicine consisting of the long-acting muscarinic antagonist (LAMA), umeclidinium bromide (UMEC), and a LABA, VI.

In the event that a product containing VI is successfully developed and commercialized, the Company will be obligated to make milestone payments to GSK which could total as much as $220.0 million if both a single-agent and a combination product or two different combination products are launched in multiple regions of the world. These potential milestone payments could be payable to GSK within the next two years. The Company is entitled to annual royalties from GSK of 15% on the first $3.0 billion of annual global net sales and 5% for all annual global net sales above $3.0 billion. Sales of single-agent LABA medicines and combination medicines would be combined for the purposes of this royalty calculation. For other products combined with a LABA from the LABA collaboration, such as UMEC/VI, royalties are upward tiering and range from the mid-single digits to 10%. However, if GSK is not selling a LABA/ICS combination product at the time that the first other LABA combination is launched, then the royalties described above for the LABA/ICS combination medicine would be applicable.

2004 Strategic Alliance

In March 2004, the Company entered into its strategic alliance with GSK. Under this alliance, GSK received an option to license exclusive development and commercialization rights to product candidates from certain of the Company's discovery programs on pre-determined terms and on an exclusive, worldwide basis.

Upon GSK's decision to license a program, GSK is responsible for funding all future development, manufacturing and commercialization activities for product candidates in that program. In addition, GSK is obligated to use diligent efforts to develop and commercialize product candidates from any program that it licenses. If the program is successfully advanced through development by GSK, the Company is entitled to receive clinical, regulatory and commercial milestone payments and royalties on any sales of medicines developed from the program. If GSK chooses not to license a program, the Company retains all rights to the program and may continue the program alone or with a third party.

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In 2005, GSK licensed the Company's bifunctional muscarinic antagonist-beta$_2$ agonist (MABA) program for the treatment of COPD, and in October 2011, the Company and GSK expanded the MABA program by adding six additional Theravance-discovered preclinical MABA compounds (the "Additional MABAs"). GSK's development, commercialization, milestone and royalty obligations under the strategic alliance remain the same with respect to '081, the lead compound in the MABA program. GSK is obligated to use diligent efforts to develop and commercialize at least one MABA within the MABA program, but may terminate progression of any or all Additional MABAs at any time and return them to the Company, at which point the Company may develop and commercialize such Additional MABAs alone or with a third party. Both GSK and the Company have agreed not to conduct any MABA clinical studies outside of the strategic alliance so long as GSK is in possession of the Additional MABAs. If a single-agent MABA medicine containing '081 is successfully developed and commercialized, the Company is entitled to receive royalties from GSK of between 10% and 20% of annual global net sales up to $3.5 billion, and 7.5% for all annual global net sales above $3.5 billion. If a MABA medicine containing '081 is commercialized only as a combination product, such as a MABA/ICS, the royalty rate is 70% of the rate applicable to sales of the single-agent MABA medicine. For single-agent MABA medicines containing an Additional MABA, the Company is entitled to receive royalties from GSK of between 10% and 15% of annual global net sales up to $3.5 billion, and 10% for all annual global net sales above $3.5 billion. For combination products containing an Additional MABA, such as a MABA/ICS, the royalty rate is 50% of the rate applicable to sales of the single-agent MABA medicine. If a MABA medicine containing '081 is successfully developed and commercialized in multiple regions of the world, the Company could earn total milestone payments of up to $125.0 million for a single-agent medicine and of up to $250.0 million for both a single-agent and a combination medicine. If a MABA medicine containing an Additional MABA is successfully developed and commercialized in multiple regions of the world, the Company could earn total milestone payments of up to $129.0 million.

In connection with the expansion of the MABA program, GSK relinquished its option right on the Company's MonoAmine Reuptake Inhibitor (MARIN) program and Angiotensin Receptor-NEP Inhibitor (ARNI) program. GSK has no further option rights on any of the Company's research or development programs under the strategic alliance.

Purchases of Common Stock under the Company's Governance Agreement and Common Stock Purchase Agreements with GSK; GSK Conversion of the Company's Class A Common Stock

On May 16, 2012, the Company issued and Glaxo Group Limited, an affiliate of GSK, purchased 10,000,000 shares of the Company's common stock at a price of $21.2887 per share, for a total investment of $212,887,000.

In addition, Glaxo Group Limited purchased shares of the Company's common stock pursuant to its periodic "top-up" rights under the Company's governance agreement with GSK dated June 4, 2004, as amended, as follows:

	Through September 30, 2012	
	Common Stock Shares Purchased	Aggregate Amounts (in thousands)
Purchase dates		
February 24, 2011	152,278	$ 3,609
May 3, 2011	261,299	$ 6,689
August 2, 2011	102,466	$ 2,020
November 1, 2011	58,411	$ 1,298
February 14, 2012	88,468	$ 1,603
August 3, 2012	316,334	$ 8,924

GSK Upfront License Fees, Milestone Payments and Revenue

Upfront license fees and milestone payments received from GSK under the LABA collaboration and strategic alliance agreements were as follows:

	Through September 30, 2012		
(in thousands)	Upfront Fees	Milestone Payments	Total
GSK Collaborations			
LABA collaboration(1)	$ 10,000	$ 50,000	$ 60,000
Strategic alliance agreement	20,000	—	20,000
Strategic alliance—LAMA license(2)	5,000	3,000	8,000
Strategic alliance—MABA program license	6,000	16,000	22,000
Total	$ 41,000	$ 69,000	$ 110,000

(1) The Company does not expect to be eligible for any additional milestones under this collaboration.

(2) In August 2004, GSK exercised its right to license the Company's LAMA program pursuant to the terms of the strategic alliance. In 2009, GSK returned the program to the Company.

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The eligible potential contingent payments related to the MABA program, which includes the Additional MABAs, are not deemed substantive due to the fact that the achievement of the event underlying the payment predominantly relates to GSK's performance of future development, manufacturing and commercialization activities for product candidates after licensing the program.

Revenue recognized from GSK under the LABA collaboration and strategic alliance agreements was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2012	2011	2012	2011
GSK Collaborations				
LABA collaboration	$ 907	$ 1,270	$ 2,722	$ 3,811
Strategic alliance agreement	—	489	—	1,858
Strategic alliance—MABA program license	523	621	1,569	1,625
Total revenue	$ 1,430	$ 2,380	$ 4,291	$ 7,294

Astellas

License, Development and Commercialization Agreement with Astellas

In November 2005, the Company entered into a global collaboration arrangement with Astellas for the development and commercialization of VIBATIV®. On January 6, 2012, Astellas exercised its right to terminate this agreement. The rights previously granted to Astellas ceased upon termination of the agreement and Astellas stopped all promotional sales efforts. Pursuant to the terms of the agreement, Astellas is entitled to a ten-year, 2% royalty on future net sales of VIBATIV®. In March 2012, the Company entered into a series of purchase agreements with Astellas for the purchase of VIBATIV® active pharmaceutical ingredient and other raw materials of up to $6.2 million and VIBATIV® finished goods inventory of up to $4.2 million, which inventory remains subject to release. As of September 30, 2012, the Company had purchased $4.3 million of active pharmaceutical ingredient and other raw materials pursuant to these purchase agreements.

In addition, beginning July 1, 2012, the Company is responsible to fund governmental rebate and governmental chargeback claims for Astellas-labeled product sales. As a result of the termination of the VIBATIV® collaboration agreement, the Company recorded a liability of $150,000 in the first quarter of 2012. At September 30, 2012, $130,000 of this accrual is reflected in deferred revenue, non-current and $20,000 of this accrual is reflected in accounts payable. The Company continues to evaluate global commercialization alternatives for VIBATIV® either with partners or alone.

Through January 6, 2012, the Company had received $191.0 million in upfront license, milestone and other fees from Astellas. The Company previously recorded these payments as deferred revenue and amortized them ratably over its estimated performance period (development and commercialization period). As a result of the termination of the VIBATIV® collaboration agreement, the development and commercialization period ended on January 6, 2012. As such, the Company recognized into revenue $125.8 million of deferred revenue related to Astellas in the first quarter of 2012, and the Company is no longer eligible to receive any further milestone payments from Astellas.

Net revenue recognized under this collaboration agreement was as follows:

(in thousands)	Three Months Ended September 30, 2012	Three Months Ended September 30, 2011	Nine Months Ended September 30, 2012	Nine Months Ended September 30, 2011
Recognition of deferred revenue	$ —	$ —	$ 125,819	$ —
Amortization of deferred revenue	—	3,244	—	9,731
Royalties from net sales of VIBATIV®	—	807	—	2,131
Proceeds from VIBATIV® delivered to Astellas	—	—	—	1,171
Cost of VIBATIV® delivered to Astellas	—	—	—	(1,177)
Astellas-labeled product sales allowance	—	—	(150)	—
Total net revenue	$ —	$ 4,051	$ 125,669	$ 11,856

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4. Available-for-Sale Securities

The following table is a summary of available-for-sale debt securities recorded in cash and cash equivalents, short-term investments, long-term marketable securities, or restricted cash in the Company's condensed consolidated balance sheets. Estimated fair values of available-for-sale securities are generally based on prices obtained from commercial pricing services:

	September 30, 2012			
(in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
U.S. government securities	$ 30,233	$ 9	$ —	$ 30,242
U.S. government agencies	107,073	69	(1)	107,141
U.S. corporate notes	98,599	45	(7)	98,637
U.S. commercial paper	37,336	1	—	37,337
Money market funds	85,634	—	—	85,634
Total	$ 358,875	$ 124	$ (8)	$ 358,991

	December 31, 2011			
(in thousands)	Amortized Cost	Gross Unrealized Gains	Gross Unrealized Losses	Estimated Fair Value
U.S. government securities	$ 66,150	$ 24	$ —	$ 66,174
U.S. government agencies	93,183	9	(17)	93,175
U.S. corporate notes	2,707	—	(2)	2,705
U.S. commercial paper	34,973	3	—	34,976
Money market funds	38,721	—	—	38,721
Total	$ 235,734	$ 36	$ (19)	$ 235,751

The following table summarizes the classification of the available-for-sale debt securities on the Company's condensed consolidated balance sheets:

(in thousands)	September 30, 2012	December 31, 2011
Cash and cash equivalents	$ 107,987	$ 38,721
Short-term investments	161,209	196,137
Long-term marketable securities	88,962	—
Restricted cash	833	893
Total	$ 358,991	$ 235,751

At September 30, 2012, all of the marketable securities have contractual maturities within two years and the average duration of marketable securities was approximately nine months. The Company does not intend to sell the investments which are in an unrealized loss position and it is unlikely that the Company will be required to sell the investments before recovery of their amortized cost basis, which may be maturity. The Company has determined that the gross unrealized losses on its marketable securities at September 30, 2012, were temporary in nature. All marketable securities with unrealized losses have been in a loss position for less than twelve months.

5. Fair Value Measurements

The Company defines fair value as the exchange price that would be received for an asset or paid to transfer a liability (an exit price) in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date.

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The Company's valuation techniques are based on observable and unobservable inputs. Observable inputs reflect readily obtainable data from independent sources, while unobservable inputs reflect the Company's market assumptions. The Company classifies these inputs into the following hierarchy:

Level 1 Inputs—Quoted prices for identical instruments in active markets.

Level 2 Inputs—Quoted prices for similar instruments in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations whose inputs are observable or whose significant value drivers are observable.

Level 3 Inputs—Unobservable inputs and little, if any, market activity for the assets.

The estimated fair values of the Company's financial assets and liabilities were as follows:

	Estimated Fair Value Measurements at Reporting Date Using:			
Types of Instruments (in thousands)	Quoted Prices in Active Markets for Identical Assets Level 1	Significant Other Observable Inputs Level 2	Significant Unobservable Inputs Level 3	Total
Assets at September 30, 2012:				
U.S. government securities	$ 30,242	$ —	$ —	$ 30,242
U.S. government agency securities	58,893	48,248	—	107,141
U.S. corporate notes	81,160	17,477	—	98,637
U.S. commercial paper	—	37,337	—	37,337
Money market funds	85,634	—	—	85,634
Total assets measured at fair value	$ 255,929	$ 103,062	$ —	$ 358,991
Liabilities at September 30, 2012:				
Convertible subordinated notes	$ 206,388	$ —	$ —	$ 206,388

	Estimated Fair Value Measurements at Reporting Date Using:			
Types of Instruments (in thousands)	Quoted Prices in Active Markets for Identical Assets Level 1	Significant Other Observable Inputs Level 2	Significant Unobservable Inputs Level 3	Total
Assets at December 31, 2011:				
U.S. government securities	$ 66,174	$ —	$ —	$ 66,174
U.S. government agency securities	55,901	37,274	—	93,175
U.S. corporate notes	2,705	—	—	2,705
U.S. commercial paper	—	34,976	—	34,976
Money market funds	38,721	—	—	38,721
Total assets measured at fair value	$ 163,501	$ 72,250	$ —	$ 235,751
Liabilities at December 31, 2011:				
Convertible subordinated notes	$ —	$ 189,588	$ —	$ 189,588

At September 30, 2012, securities with a total fair value of $11.1 million were measured using Level 1 inputs in comparison to December 31, 2011, at which time the securities had a fair value of $11.4 million and were measured using Level 2 inputs. The transfer to Level 1 from Level 2 was primarily the result of increased trading volume of the securities at and around September 30, 2012, compared to December 31, 2011.

At September 30, 2012, securities with a total fair value of $5.0 million were measured using Level 2 inputs in comparison to December 31, 2011, at which time the securities had a fair value of $5.0 million and were measured using Level 1 inputs. The transfer to Level 2 from Level 1 was primarily the result of decreased trading volume of the securities at and around September 30, 2012, compared to December 31, 2011.

At September 30, 2012, convertible subordinated notes with a total fair value of $206.4 million were measured using Level 1 inputs in comparison to December 31, 2011, at which time the securities had a fair value of $189.6 million and were measured using Level 2 inputs. The transfer to Level 1 from Level 2 was primarily the result of increased trading volume of the convertible subordinated notes at and around September 30, 2012, compared to December 31, 2011.

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6. Long-Term Debt

Long-term debt outstanding is summarized as follows:

(in thousands)	September 30, 2012	December 31, 2011
Convertible subordinated notes	$ 172,500	$ 172,500

Convertible Subordinated Notes

In January 2008, the Company closed an underwritten public offering of $172.5 million aggregate principal amount of unsecured convertible subordinated notes which will mature on January 15, 2015. The financing raised proceeds, net of issuance costs, of $166.7 million. The notes bear interest at the rate of 3.0% per year, that is payable semi-annually in arrears in cash on January 15 and July 15 of each year, beginning on July 15, 2008.

The notes are convertible, at the option of the holder, into shares of the Company's common stock at an initial conversion rate of 38.6548 shares per $1,000 principal amount of the notes, subject to adjustment in certain circumstances, which represents an initial conversion price of approximately $25.87 per share. Holders of the notes will be able to require the Company to repurchase some or all of their notes upon the occurrence of a fundamental change (as defined in the indenture establishing the terms of the rates) at 100% of the principal amount of the notes being repurchased plus accrued and unpaid interest. The Company could not redeem the notes prior to January 15, 2012. On or after January 15, 2012 and prior to the maturity date, the Company, upon notice of

redemption, may redeem for cash all or part of the notes if the last reported sale price of its common stock has been greater than or equal to 130% of the conversion price then in effect for at least 20 trading days during any 30 consecutive trading day period prior to the date on which it provides notice of redemption. The redemption price will equal 100% of the principal amount of the notes to be redeemed, plus accrued and unpaid interest up to but excluding the redemption date. As of September 30, 2012, the Company had not provided notice of redemption or redeemed any of the notes.

Debt issuance costs, which were capitalized and included in other long-term assets, are being amortized on a straight-line basis over the life of the notes. Unamortized debt issuance costs totaled $1.9 million as of September 30, 2012. Amortization expense was $0.2 million for both the three months ended September 30, 2012 and 2011 and $0.6 million for both the nine months ended September 30, 2012 and 2011.

7. Commitments and Contingencies

Guarantees and Indemnifications

The Company indemnifies its officers and directors for certain events or occurrences, subject to certain limits. The Company believes the fair value of these indemnification agreements is minimal. Accordingly, the Company has not recognized any liabilities relating to these agreements as of September 30, 2012.

Purchase Obligation

The Company entered into a series of purchase agreements for VIBATIV® active pharmaceutical ingredient and other raw materials of up to $6.2 million and VIBATIV® finished goods inventory of up to $4.2 million, which inventory remains subject to release. As of September 30, 2012 the Company had purchased $4.3 million of active pharmaceutical ingredient and other raw materials pursuant to these purchase agreements.

8. Stock-Based Compensation and Stockholders' Equity (Net Capital Deficiency)

Equity Incentive Plans

In May 2012, the Company adopted the 2012 Equity Incentive Plan (2012 Plan). The number of shares of the Company's common stock available for issuance under the 2012 Plan is equal to 6,500,000 shares plus up to 12,667,411 additional shares that may be added to the 2012 Plan in connection with the forfeiture, repurchase, cash settlement or termination of awards outstanding under the 2004 Equity Incentive Plan (2004 Plan), the 2008 New Employee Equity Incentive Plan, the 1997 Stock Plan and the Long-Term Stock Option Plan (collectively, the "Prior Plans") as of December 31, 2011. While a maximum of 12,667,411 shares could be added to the 2012 Plan from the Prior Plans, since this assumes that all the awards outstanding on December 31, 2011 will be forfeited, repurchased, cash settled or terminated, the actual number to be added to the 2012 Plan share reserve may be less. Upon adoption of the 2012 Plan, the Company reserved 6,500,000 shares of common stock for issuance under the 2012 Plan. The 2012 Plan reserve was also reduced by the number of stock awards granted under the 2004 Plan on or after January 1, 2012. No additional awards have been or will be made after May 15, 2012 under the 2004 Plan. Stock options and SARS will reduce the 2012 Plan reserve by one share for every share granted, and stock awards other than options and SARs granted will reduce the 2012 Plan share reserve

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by 1.45 shares for every share granted. The 2012 Plan share reserve was also reduced by the number of stock awards granted under the 2004 Plan on or after January 1, 2012, using the same ratios described. As of September 30, 2012, total shares remaining available for issuance under the 2012 Plan were approximately 5,044,905.

The 2012 Plan provides for the grant of incentive stock options, nonstatutory stock options, restricted stock awards, stock unit awards and stock appreciation rights ("SARs") to employees, non-employee directors and consultants of the Company. Stock options may be granted with an exercise price not less than the fair market value of the common stock on the grant date. Stock options granted to employees generally have a maximum term of 10 years and vest over a four year period from the date of grant; 25% vest at the end of one year, and 75% vest monthly over the remaining three years. The Company may grant options with different vesting terms from time to time. Unless an employee's termination of service is due to disability or death, upon termination of service, any unexercised vested options will be forfeited at the end of three months or the expiration of the option, whichever is earlier.

Employee Stock Purchase Plan

As of September 30, 2012, a total of 2,025,000 shares of common stock were approved and authorized for issuance under the ESPP. As of September 30, 2012, total shares remaining available for issuance under the ESPP were 476,977.

Stock-Based Compensation Expense

The allocation of stock-based compensation expense included in the condensed consolidated statements of operations was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2012	2011	2012	2011
Research and development	$ 3,259	$ 3,510	$ 10,329	$ 10,021
General and administrative	2,571	3,380	7,715	8,685
Total stock-based compensation expense	$ 5,830	$ 6,890	$ 18,044	$ 18,706

As of September 30, 2012, unrecognized compensation expense, net of expected forfeitures, was as follows: $6.5 million related to unvested stock options; $16.9 million related to unvested RSUs; and $25.6 million related to unvested RSAs (excludes performance-contingent RSAs).

Compensation Awards

The Company granted the following compensation awards:

	Nine Months Ended September 30, 2012		Nine Months Ended September 30, 2011	
	Number of Compensation Awards Granted	Weighted-Average Exercise Price/Fair Value	Number of Compensation Awards Granted	Weighted-Average Exercise Price/Fair Value
2004 and 2012 Plans				
Stock options	269,000	$ 21.83	582,250	$ 22.06
RSUs time-based	528,381	18.45	465,000	25.03
RSAs time-based	402,500	18.11	1,168,000	24.59
RSAs performance-contingent(1)	44,500	18.11	1,315,000	24.26

(1) In 2011, the Compensation Committee of the Company's Board of Directors approved the grant of 1,290,000 performance-contingent RSAs to senior management. These grants have dual triggers of vesting based upon the achievement of certain performance conditions over a six-year timeframe from 2011-2016 and continued employment, both of which must be satisfied in order for the RSAs to vest. Expense associated with these RSAs would be recognized, if at all, during these years depending on the probability of meeting the performance conditions. The maximum potential expense associated with the RSAs could be up to approximately $31.9 million (allocated as $6.3 million for research and development expense and $25.6 million for general and administrative expense) if all of the performance conditions are achieved on time. As of September 30, 2012, the Company had determined that the achievement of the requisite performance conditions was not probable and, as a result, no compensation

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expense has been recognized. As the RSAs are dependent upon the achievement of certain performance conditions, the expense associated with the RSAs may vary significantly from period to period.

In February 2012, the Compensation Committee of the Company's Board of Directors approved the grant of 44,500 performance-contingent RSAs to senior management. These grants are subject to forfeiture unless one of three possible performance goals is achieved by December 31, 2013. As of September 30, 2012, the Company had determined that the achievement of one of three possible performance conditions was probable and, as a result, compensation expense of $0.3 million was recognized in the third quarter of 2012, and the remaining unrecognized expense will be recognized over the remaining vesting period.

Valuation Assumptions

The range of weighted-average assumptions used to estimate the fair value of stock options granted was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2012	2011	2012	2011
Employee stock options				
Risk-free interest rate	0.83%-0.86%	1.20%-2.17%	0.74%-1.17%	1.20%-2.57%
Expected term (in years)	6	6	5-6	5-6
Volatility	57%	53%	55%-60%	49%-55%
Dividend yield	—%	—%	—%	—%
Weighted-average estimated fair value of stock options granted	$ 14.31	$ 9.74	$ 11.41	$ 11.15

Stockholders' Equity

During the nine months ended September 30, 2012, approximately 882,666 options were exercised at a weighted-average exercise price of $8.28 per share, for total cash proceeds of approximately $7.3 million.

9. Income Taxes

The Company did not record a provision for income taxes for the nine months ended September 30, 2012, because it is expected to generate a taxable net operating loss for the fiscal year ending December 31, 2012. In addition, the deferred tax assets continue to be treated as having no current value and remain subject to a full valuation allowance.

10. Subsequent Events

Collaboration Arrangements

Alfa Wassermann

On October 1, 2012, the Company entered into a development and commercialization agreement with Alfa Wassermann S.p.A. for velusetrag (or TD-5108), the Company's investigational 5-HT4 agonist in development for gastrointestinal motility disorders. Under the agreement, the companies will collaborate in the execution of a two-part Phase 2 program to test the efficacy, safety and tolerability of velusetrag in the treatment of patients with gastroparesis. Alfa Wassermann has an exclusive option to develop and commercialize velusetrag in the European Union, Russia, China, Mexico and certain other countries, while the Company retains full rights to velusetrag in the US, Canada, Japan and certain other countries. The Company is entitled to funding for the Phase 2 program and, if the option is exercised, a $10.0 million option fee, potential future development, regulatory and sales payments totaling up to $53.5 million, and royalties on net sales by Alfa Wassermann ranging from the low teens to 20%.

Merck

On October 15, 2012, the Company signed a collaboration agreement with Merck, known as MSD outside the United States and Canada, to discover, develop and commercialize novel small molecule therapeutics directed towards a target being investigated for the treatment of hypertension and heart failure. In exchange for granting Merck a worldwide, exclusive license to the Company's therapeutic candidates, the Company will receive a $5.0 million upfront payment, funding for research, and be eligible for potential future payments totaling up to $148.0 million for the first indication and royalties on worldwide annual net sales of any products derived from the collaboration. The Company will be responsible for discovery and Merck will be responsible for and fund

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all development and commercialization activities. The initial research term is twelve months, with optional extensions by mutual agreement, and Merck can terminate the agreement at any time.

R-Pharm CJSC

On October 19, 2012, the Company entered into two separate development and commercialization agreements with R-Pharm CJSC. The first was for TD-1792, the Company's investigational glycopeptide-cephalosporin heterodimer antibiotic for the treatment of resistant Gram-positive infections, and the second was for telavancin. In both of the agreements, the Company granted R-Pharm exclusive development and commercialization rights in Russia, Ukraine, other member countries of the Commonwealth of Independent States, and Georgia. The Company is eligible to receive up to $2.0 million in near-term licensing fees, and potential future development payments of $4.0 million and sales payments of $6.0 million. The Company is entitled to receive a 15% royalty on net sales of TD-1792 and a 25% royalty on net sales of telavancin.

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Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Forward-Looking Statements

The information in this discussion contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (Securities Act), and Section 21E of the Securities Exchange Act of 1934, as amended. Such forward-looking statements involve substantial risks, uncertainties and assumptions. All statements contained herein that are not of historical fact, including, without limitation, statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans, intentions, expectations, goals and objectives, may be forward-looking statements. The words "anticipates," "believes," "designed," "estimates," "expects," "intends," "may," "objective," "plans," "projects," "pursue," "will," "would" and similar expressions (including the negatives thereof) are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We may not actually achieve the plans, intentions, expectations or objectives disclosed in our forward-looking statements and the assumptions underlying our forward-looking statements may prove incorrect. Therefore, you should not place undue reliance on our forward-looking statements. Actual results or events could materially differ from the plans, intentions, expectations and objectives disclosed in the forward-looking statements that we make. Factors that we believe could cause actual results or events to differ materially from our forward-looking statements include, but are not limited to, those discussed below in "Risk Factors" in Item 1A of Part II and in "Management's Discussion and Analysis of Financial Condition and Results of Operations" in this Item 2 of Part I. All forward-looking statements in this document are based on information available to us as of the date hereof and we assume no obligation to update any such forward-looking statements.

OVERVIEW

Executive Summary

Theravance is a biopharmaceutical company with a pipeline of internally discovered product candidates and strategic collaborations with pharmaceutical companies. We are focused on the discovery, development and commercialization of small molecule medicines across a number of therapeutic areas including respiratory disease, bacterial infections, and central nervous system (CNS)/pain. Our key programs include: Relvar™ or Breo™ (FF/VI), umeclidinium bromide/vilanterol (UMEC/VI) and MABA (Bifunctional Muscarinic Antagonist-Beta$_2$ Agonist), each partnered with GlaxoSmithKline plc (GSK), and our oral Peripheral Mu Opioid Receptor Antagonist program. By leveraging our proprietary insight of multivalency to drug discovery, we are pursuing a best-in-class strategy designed to discover superior medicines in areas of significant unmet medical need.

In the third quarter of 2012, our net loss was $34.7 million, an increase of 13% from $30.6 million in the third quarter of 2011. In the first nine months of 2012, our net income was $12.8 million, a change of $91.1 million from a net loss of $78.3 million in the first nine months of 2011. Net income in the nine months ended September 30, 2012 reflects the recognition of deferred revenue of $125.7 million from our global collaboration arrangement with Astellas Pharma Inc. (Astellas) for the development and commercialization of VIBATIV®. This recognition resulted from Astellas' January 6, 2012 termination of our agreement with them. In the third quarter of 2012, our research and development expenses were $27.0 million, a decrease of 3% from $27.8 million in the third quarter of 2011. In the first nine months of 2012, our research and development expenses were $89.8 million, an increase of 26% from $71.1 million in the first nine months of 2011. Cash, cash equivalents, short-term investments, and long-term marketable securities totaled $362.4 million at September 30, 2012, an increase of $121.5 million from December 31, 2011. The increase was primarily due to net proceeds of $223.0 million received from our private placements of common stock to an affiliate of GSK and $7.3 million received from exercises of employee stock options, partially offset by cash used in operations of $103.3 million.

Programs

Respiratory Programs with GSK

Fluticasone Furoate/Vilanterol (FF/VI)

FF/VI is an investigational once-daily inhaled corticosteroid (ICS)/long-acting beta2 agonist (LABA) combination treatment, comprising fluticasone furoate and vilanterol, for the maintenance treatment of patients with chronic obstructive pulmonary disease (COPD) and patients with asthma. FF/VI is

administered by a new dry powder inhaler called Ellipta™. Relvar™ (FF/VI for the European Union (EU) and Japan), Breo™ (FF/VI for the US), and Ellipta™ (for the EU, US and Japan) are proposed brand names and use of these brand names has not yet been approved by any regulatory authority.

In September 2012, GSK and Theravance announced that that the New Drug Application (NDA) for FF/VI for patients with COPD was accepted by the U.S. Food and Drug Administration (FDA) indicating that the application is sufficiently complete to permit a substantive review. The Prescription Drug User Fee Act goal date was confirmed as May 12, 2013. GSK and Theravance also

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reported that the Marketing Authorization Application for FF/VI for COPD and asthma was validated by the European Medicines Agency (EMA). In addition, GSK also submitted a Japanese New Drug Application for FF/VI for patients with COPD and asthma on September 25, 2012.

Umeclidinium Bromide/Vilanterol (UMEC/VI)

UMEC/VI is a once-daily investigational medicine, combining a long-acting muscarinic antagonist (LAMA) umeclidinium bromide (UMEC), and a LABA, VI, for the maintenance treatment of patients with COPD. UMEC/VI is administered by the Ellipta™ dry powder inhaler.

In August 2012, GSK and Theravance announced the completion of the Phase 3 program involving approximately 6,000 patients with COPD. The pivotal program for UMEC/VI includes two 24-week efficacy studies that compared the combination UMEC/VI, its components and placebo, two 24-week active comparator studies that compared the combination with tiotropium, a widely prescribed maintenance bronchodilator for COPD, and a 52-week safety study. Two non-pivotal 12-week crossover exercise studies will also be included in the registrational package. These studies support GSK's plans to commence global regulatory submissions for UMEC/VI from the end of 2012.

Inhaled Bifunctional Muscarinic Antagonist-Beta2 Agonist (MABA)

GSK961081 ('081) is an investigational, single molecule bifunctional bronchodilator with both muscarinic antagonist and beta2 receptor agonist activities. The results from the Phase 2b study and a number of non-clinical studies will inform the selection of the most appropriate dose and dosing interval for '081 and progression to Phase 3.

Central Nervous System (CNS)/Pain Program

Oral Peripheral Mu Opioid Receptor Antagonist — TD-1211

TD-1211 is an investigational once-daily, orally administered, peripherally selective, multivalent inhibitor of the mu opioid receptor designed with a goal of alleviating gastrointestinal side effects of opioid therapy without affecting analgesia. In July 2012, Theravance announced positive topline results from the Phase 2b Study 0084, the key study in the Phase 2b program evaluating TD-1211 as potential treatment for chronic, non-cancer pain patients with opioid-induced constipation. The Phase 2b program consists of three studies (0074, 0076 and 0084) designed to evaluate doses and dosing regimens for Phase 3. The results support progression into Phase 3 development.

Monoamine Reuptake Inhibitor — TD-9855

TD-9855 is an investigational norepinephrine and serotonin reuptake inhibitor for the treatment of central nervous system conditions such as Attention-Deficit/Hyperactivity Disorder (ADHD) and chronic pain. TD-9855 is being evaluated in an ongoing Phase 2 safety and efficacy study in adults with ADHD. In addition, Theravance plans to initiate a Phase 2 study with TD-9855 in patients with fibromyalgia in the next few months.

Collaboration Arrangements

GSK

LABA collaboration

In November 2002, we entered into our LABA collaboration with GSK to develop and commercialize once-daily LABA products for the treatment of COPD and asthma. For the treatment of COPD, the collaboration is developing two combination products: FF/VI, an investigational once-daily combination medicine consisting of a LABA, VI, and an ICS, fluticasone furoate (FF) and umeclidinium bromide/vilanterol (UMEC/VI), a once-daily investigational medicine combining a LAMA, UMEC, with a LABA, VI. For the treatment of asthma, the collaboration is developing FF/VI. The FF/VI program is aimed at developing a once-daily combination LABA/ICS to succeed GSK's Advair®/Seretide™ (salmeterol and fluticasone as a combination) franchise, which had reported 2011 sales of approximately $8.1 billion, and to compete with Symbicort® (formoterol and budesonide as a combination), which had reported 2011 sales of approximately $3.1 billion. UMEC/VI, which is also a combination product, is targeted as an

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alternative treatment option to Spiriva® (tiotropium), a once-daily, single-mechanism bronchodilator, which had reported 2011 sales of approximately $4.2 billion.

In the event that a product containing VI is successfully developed and commercialized, we will be obligated to make milestone payments to GSK which could total as much as $220.0 million if both a single-agent and a combination product or two different combination products are launched in multiple regions of the world. These potential milestone payments could be payable to GSK within the next two years. We are entitled to annual royalties from GSK of 15% on the first $3.0 billion of annual global net sales and 5% for all annual global net sales above $3.0 billion. Sales of single-agent LABA medicines and combination medicines would be combined for the purposes of this royalty calculation. For other products combined with a LABA from the LABA collaboration, such as UMEC/VI, royalties are upward tiering and range from the mid-single digits to 10%. However, if GSK is not selling a LABA/ICS

combination product at the time that the first other LABA combination is launched, then the royalties described above for the LABA/ICS combination medicine would be applicable.

2004 Strategic Alliance

In March 2004, we entered into our strategic alliance with GSK. Under this alliance, GSK received an option to license exclusive development and commercialization rights to product candidates from certain of our discovery programs on pre-determined terms and on an exclusive, worldwide basis. Upon GSK's decision to license a program, GSK is responsible for funding all future development, manufacturing and commercialization activities for product candidates in that program. In addition, GSK is obligated to use diligent efforts to develop and commercialize product candidates from any program that it licenses. If the program is successfully advanced through development by GSK, we are entitled to receive clinical, regulatory and commercial milestone payments and royalties on any sales of medicines developed from the program. If GSK chooses not to license a program, we retain all rights to the program and may continue the program alone or with a third party.

In 2005, GSK licensed our MABA program for the treatment of COPD, and in October 2011, we and GSK expanded the MABA program by adding six additional Theravance-discovered preclinical MABA compounds (the "Additional MABAs"). GSK's development, commercialization, milestone and royalty obligations under the strategic alliance remain the same with respect to '081, the lead compound in the MABA program. GSK is obligated to use diligent efforts to develop and commercialize at least one MABA within the MABA program, but may terminate progression of any or all Additional MABAs at any time and return them to us, at which point we may develop and commercialize such Additional MABAs alone or with a third party. Both GSK and we have agreed not to conduct any MABA clinical studies outside of the strategic alliance so long as GSK is in possession of the Additional MABAs. If a single-agent MABA medicine containing '081 is successfully developed and commercialized, we are entitled to receive royalties from GSK of between 10% and 20% of annual global net sales up to $3.5 billion, and 7.5% for all annual global net sales above $3.5 billion. If a MABA medicine containing '081 is commercialized only as a combination product, such as a MABA/ICS, the royalty rate is 70% of the rate applicable to sales of the single-agent MABA medicine. For single-agent MABA medicines containing an Additional MABA, we are entitled to receive royalties from GSK of between 10% and 15% of annual global net sales up to $3.5 billion, and 10% for all annual global net sales above $3.5 billion. For combination products containing an Additional MABA, such as a MABA/ICS, the royalty rate is 50% of the rate applicable to sales of the single-agent MABA medicine. If a MABA medicine containing '081 is successfully developed and commercialized in multiple regions of the world, we could earn total milestone payments of up to $125.0 million for a single-agent medicine and of up to $250.0 million for both a single-agent and a combination medicine. If a MABA medicine containing an Additional MABA is successfully developed and commercialized in multiple regions of the world, we could earn total milestone payments of up to $129.0 million.

In connection with the expansion of the MABA program, GSK relinquished its option right on our MonoAmine Reuptake Inhibitor (MARIN) program and Angiotensin Receptor-NEP Inhibitor (ARNI) program. GSK has no further option rights on any of our research or development programs under the strategic alliance.

Purchases of Common Stock under our Governance Agreement and Common Stock Purchase Agreements with GSK

On May 16, 2012, we issued and Glaxo Group Limited, an affiliate of GSK, purchased 10,000,000 shares of our common stock at a price of $21.2887 per share, for a total investment of $212,887,000.

In addition, in 2012, Glaxo Group Limited, pursuant to its periodic "top-up" rights under our governance agreement with GSK dated June 4, 2004, as amended, purchased shares of our common stock as follows:

	Common Stock Shares Purchased	Aggregate Amounts (in millions)
Purchase dates		
February 14, 2012	88,468	$ 1.6
August 3, 2012	316,334	$ 8.9

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GSK Upfront License Fees, Milestone Payments and Revenue

Revenue recognized from GSK under the LABA collaboration and strategic alliance agreements was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in millions)	2012	2011	2012	2011
GSK Collaborations				
LABA collaboration	$ 0.9	$ 1.3	$ 2.7	$ 3.8
Strategic alliance agreement	—	0.5	—	1.9
Strategic alliance—MABA program license	0.5	0.6	1.6	1.6
Total revenue	$ 1.4	$ 2.4	$ 4.3	$ 7.3

Astellas

License, Development and Commercialization Agreement with Astellas

In November 2005, we entered into a global collaboration arrangement with Astellas for the development and commercialization of VIBATIV®. On January 6, 2012, Astellas exercised its right to terminate this agreement. The rights previously granted to Astellas ceased upon termination of the agreement and Astellas stopped all promotional sales efforts. Pursuant to the terms of the agreement, Astellas is entitled to a ten-year, 2% royalty on future net sales of VIBATIV®. In March 2012, we entered into a series of purchase agreements with Astellas for the purchase of VIBATIV® active pharmaceutical ingredient and other raw materials of up to $6.2 million and VIBATIV® finished goods inventory of up to $4.2 million, which inventory remains subject to release. As of September 30, 2012, we had purchased $4.3 million of active pharmaceutical ingredient and other raw materials pursuant to these purchase agreements.

In addition, beginning July 1, 2012, we are responsible to fund governmental rebate and governmental chargeback claims for Astellas-labeled product sales. As a result of the termination of the VIBATIV® collaboration agreement, we recorded a liability of $150,000. At September 30, 2012, $130,000 is reflected in deferred revenue, non-current and $20,000 is reflected in accounts payable.

Through January 6, 2012, we had received $191.0 million in upfront license, milestone and other fees from Astellas. We previously recorded these payments as deferred revenue and amortized them ratably over the estimated performance period (development and commercialization period). As a result of the termination of the VIBATIV® collaboration agreement, the development and commercialization period ended on January 6, 2012. As such, we recognized into revenue $125.8 million of deferred revenue related to Astellas in the first quarter of 2012, and we are no longer eligible to receive any further milestone payments from Astellas.

Net revenue recognized under this collaboration agreement was as follows:

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in millions)	2012	2011	2012	2011
Recognition of deferred revenue	$ —	$ —	$ 125.8	$ —
Amortization of deferred revenue	—	3.2	—	9.7
Royalties from net sales of VIBATIV®	—	0.8	—	2.1
Proceeds from VIBATIV® delivered to Astellas	—	—	—	1.2
Cost of VIBATIV® delivered to Astellas	—	—	—	(1.2)
Astellas-labeled product sales allowance	—	—	(0.1)	—
Total net revenue	$ —	$ 4.0	$ 125.7	$ 11.8

VIBATIV®

VIBATIV® (telavancin) is a bactericidal, once-daily injectable antibiotic developed by us for the treatment of Gram-positive infections. The FDA has approved VIBATIV® for the treatment of complicated skin and skin structure infections (cSSSI) caused by susceptible Gram-positive bacteria including both methicillin-resistant (MRSA) and methicillin-susceptible strains of *Staphylococcus aureus* in adult patients. VIBATIV® is also approved in Canada for the treatment of cSSSI in adult patients. In September 2011, the

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European Commission granted marketing authorization for VIBATIV® for the treatment of adults with nosocomial pneumonia, including ventilator-associated pneumonia, known or suspected to be caused by MRSA when other alternatives are not suitable. However, in May 2012, the European Commission suspended this marketing authorization because the single-source drug product supplier did not meet the Good Manufacturing Practice (GMP) requirements for the manufacture of VIBATIV®. In September 2012, we received notice that the FDA's Anti-Infective Drugs Advisory Committee (AIDAC) plans to discuss the NDA for VIBATIV® for nosocomial pneumonia (NP) at a meeting on November 29, 2012.

We are evaluating global commercialization alternatives for VIBATIV® either with partners or alone.

Due to manufacturing issues at the single-source supplier of VIBATIV® drug product, VIBATIV® is currently subject to critical product shortages and regional supply outages in the U.S. In May 2012, we entered into a Technology Transfer and Supply Agreement with Hospira Worldwide, Inc. (Hospira) and technology transfer activities are in process. We must obtain regulatory approval for VIBATIV® drug product that will be manufactured at Hospira's facility before any such product may be sold, and this regulatory approval process could extend through mid-2013.

Critical Accounting Policies and the Use of Estimates

As of the date of the filing of this quarterly report, we believe there have been no material changes or additions to our critical accounting policies and estimates during the nine months ended September 30, 2012 compared to those discussed in our 2011 Annual Report on Form 10-K filed on February 27, 2012, except as follows:

Inventories are stated at the lower of cost or market value. Cost is determined using an average cost basis. Inventories include VIBATIV® active pharmaceutical ingredient and other raw materials of $4.3 million and work-in-process of $0.8 million at September 30, 2012. VIBATIV® is a U.S. Food and Drug Administration (FDA) approved drug. If information becomes available that suggests the inventories may not be realizable, we may be required to expense a portion or all of the capitalized inventory costs.

RESULTS OF OPERATIONS

Revenue

Revenue, as compared to the prior year periods, was as follows:

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
(in millions, except percentages)	2012	2011	$	%	2012	2011	$	%
Revenue	$ 1.4	$ 6.4	$ (5.0)	(78)%	$ 130.0	$ 19.2	$ 110.8	577%

We recognized revenue from the amortization of upfront license fees and milestone payments related to our GSK LABA collaboration and strategic alliance agreements and, during the nine month period ended September 30, 2012, from our Astellas telavancin collaboration, which was terminated on January 6, 2012. In addition, we recognized revenue related to our Astellas telavancin collaboration from royalties from net sales of VIBATIV® and from the impact of VIBATIV® inventory transfers or dispositions.

Revenue decreased 78% to $1.4 million in the third quarter of 2012 from the comparable period in 2011. Revenue increased 577% to $130.0 million in the first nine months of 2012 from the comparable period in 2011. The decrease in the three months ended September 30, 2012 and the increase in the first

nine months of 2012 reflects the accelerated recognition of deferred revenue of $125.7 million from our global collaboration arrangement with Astellas for the development and commercialization of VIBATIV® in the first quarter of 2012. This accelerated recognition was the result of the termination of the Astellas agreement on January 6, 2012.

Upfront license fees and milestone payments received from GSK under the LABA collaboration and strategic alliance agreements and from Astellas under the telavancin collaboration were as follows:

	Through September 30, 2012		
(in millions)	Upfront License and Other Fees	Milestone Payments	Total
GSK Collaborations			
LABA collaboration(1)	$ 10.0	$ 50.0	$ 60.0
Strategic alliance agreement	20.0	—	20.0
Strategic alliance—LAMA license(2)	5.0	3.0	8.0
Strategic alliance—MABA program license	6.0	16.0	22.0
Astellas License agreement(3)	70.0	121.0	191.0
Total	$ 111.0	$ 190.0	$ 301.0

(1) We do not expect to be eligible for any additional milestones under this collaboration.

(2) In August 2004, GSK exercised its right to license our LAMA program pursuant to the terms of the strategic alliance. In 2009, GSK returned the program to us.

(3) This agreement was terminated on January 6, 2012.

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Upfront fees and certain milestone payments received from GSK have been deferred and are being amortized ratably into revenue over the estimated performance period. Future revenue will include the ongoing amortization of upfront and milestone payments earned. We periodically review and, if necessary, revise the estimated periods of our performance pursuant to these contracts.

Research & Development

Research and development expenses, as compared to the prior year periods, were as follows:

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
(in millions, except percentages)	2012	2011	$	%	2012	2011	$	%
Employee-related	$ 9.0	$ 8.7	$ 0.3	3%	$ 28.7	$ 25.5	$ 3.2	13%
External-related	8.8	9.5	(0.7)	(7)%	32.9	17.9	15.0	84%
Stock-based compensation	3.3	3.5	(0.2)	(6)%	10.3	10.0	0.3	3%
Facilities, depreciation and other allocated	5.9	6.1	(0.2)	(3)%	17.9	17.7	0.2	1%
Total expenses	$ 27.0	$ 27.8	$ (0.8)	(3)%	$ 89.8	$ 71.1	$ 18.7	26%

R&D expenses decreased 3% to $27.0 million in the third quarter of 2012 from the comparable period in 2011. This decrease was primarily due to lower external expenses resulting from the completion of Phase 2 clinical activities related to TD-1211; partially offset by higher external expenses related to MARIN Phase 2 studies and preparation for the FDA advisory committee meeting concerning the VIBATIV® NDA for nosocomial pneumonia scheduled for November 2012. R&D expenses increased 26% to $89.8 million in the first nine months of 2012 from the comparable period in 2011. This increase was primarily due to Phase 2 clinical costs related to our program for opioid-induced constipation with TD-1211, costs associated with our preclinical and late-stage discovery programs and higher employee-related expenses.

We anticipate R&D expenses for 2012 to increase relative to 2011. R&D expenses in 2012 will be driven largely by higher employee-related expenses, costs associated with our continued development efforts in our program for opioid-induced constipation with TD-1211, our MARIN program with TD-9855, and costs associated with our earlier stage clinical programs, preclinical studies and late-stage discovery programs. We have not provided program costs in detail because we do not track, and have not tracked, all of the individual components (specifically the internal cost components) of our research and development expenses on a program basis. We do not have the systems and processes in place to accurately capture these costs on a program basis.

General and administrative

General and administrative expenses, as compared to the prior year periods, were as follows:

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
(in millions, except percentages)	2012	2011	$	%	2012	2011	$	%
General and administrative expense	$ 7.8	$ 7.8	$ —	—%	$ 23.2	$ 22.2	1.0	5%

G&A expenses remained flat in the third quarter of 2012 from the comparable period in 2011. G&A expenses increased 5% to $23.2 million in the first nine months of 2012 from the comparable period in 2011. This increase was primarily due to an increase in external legal fees and professional services costs in connection with the evaluation of global commercialization alternatives related to VIBATIV® and other strategic initiatives and higher employee-related expenses, partially offset by decreases in stock-based compensation expense and facilities-related costs. Stock-based compensation expense was $2.6 million in the third quarter of 2012,

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compared to $3.4 million in the same period of 2011 and $7.7 million in the nine months ended September 30, 2012, compared to $8.7 million in the same period of 2011.

We anticipate G&A expenses for 2012 to increase slightly relative to 2011, primarily due to the transfer of certain ongoing VIBATIV® related activities following the termination by Astellas of the collaboration agreement in January 2012.

Interest income

Interest income, as compared to the prior year periods, was as follows:

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
(in millions, except percentages)	2012	2011	$	%	2012	2011	$	%
Interest income	$ 0.2	$ 0.1	$ 0.1	100%	$ 0.3	$ 0.3	$ —	—%

Interest income remained relatively flat in the third quarter and first nine months of 2012 from the comparable periods in 2011.

Interest expense

Interest expense, as compared to the prior year periods, was as follows:

	Three Months Ended September 30,		Change		Nine Months Ended September 30,		Change	
(in millions, except percentages)	2012	2011	$	%	2012	2011	$	%
Interest expense	$ 1.5	$ 1.5	$ —	—%	$ 4.5	$ 4.5	$ —	—%

Interest expense is primarily comprised of interest expense and amortization of debt issuance costs from our convertible subordinated notes issued in January 2008.

LIQUIDITY AND CAPITAL RESOURCES

Liquidity

Since our inception, we have financed our operations primarily through private placements and public offerings of equity and debt securities and payments received under corporate collaboration arrangements. As of September 30, 2012, we had $362.4 million in cash, cash equivalents and marketable securities, excluding $0.8 million in restricted cash that was pledged as collateral for certain of our leases. On May 16, 2012, we issued and Glaxo Group Limited, an affiliate of GSK, purchased 10,000,000 shares of our common stock at a price of $21.2887 per share, for net proceeds of $212.5 million.

We expect to incur substantial expenses as we continue our drug discovery and development efforts, particularly to the extent we advance our product candidates into and through clinical studies, which are very expensive. For example, in July 2012, we announced positive results from the key study in our Phase 2b program with TD-1211 in our Peripheral Mu Opioid Receptor Antagonist program for opioid-induced constipation. Though we seek to partner this program, we may choose to progress TD-1211 into Phase 3 studies by ourselves, which would increase our operating expenses substantially. In addition, we initiated a Phase 2 study with TD-9855 in the MARIN program in late 2011 and we are planning a second Phase 2 study with TD-9855. We also intend to invest in other assets in our pipeline, including programs in earlier-stage clinical development and late-stage discovery.

On January 6, 2012, Astellas exercised its right to terminate our collaboration agreement for VIBATIV®. In March 2012, we entered into a series of purchase agreements for VIBATIV® active pharmaceutical ingredient and other raw materials of up to $6.2 million and VIBATIV® finished goods inventory of up to $4.2 million, which inventory remains subject to release. As of September 30, 2012, we had purchased $4.3 million of active pharmaceutical ingredient and other raw materials.

We believe that our cash, cash equivalents and marketable securities will be sufficient to meet our anticipated operating needs for at least the next twelve months based upon current operating plans, milestone and royalty forecasts and spending assumptions. If our current operating plans, milestone and royalty forecasts or spending assumptions change, we may require additional funding sooner in the form of public or private equity offerings or debt financings. Furthermore, if in our view favorable financing opportunities arise, we may seek additional funding at any time. However, future financing may not be available in amounts or on terms acceptable to us, if at all. This could leave us without adequate financial resources to fund our operations as presently conducted. In addition, we regularly explore debt restructuring and/or reduction alternatives, including through tender offers, redemptions, repurchases or otherwise, all consistent with the terms of our debt agreements.

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Cash Flows

Cash flows, as compared to the prior year period, were as follows:

	Nine Months Ended September 30,	
(in millions)	2012	2011
Net cash used in operating activities	$ (103.3)	$ (63.0)
Net cash used in investing activities	$ (58.4)	$ (60.4)
Net cash provided by financing activities	$ 229.2	$ 22.8

Cash used in operations increased $40.3 million for the nine months ended September 30, 2012, compared to the same period in 2011, primarily due to higher uses of cash for operating liabilities resulting from an increase in R&D activity and purchase of inventory.

Cash used in investing activities remained relatively the same for the nine months ended September 30, 2012, compared to the same period in 2011.

Cash provided by financing activities increased $206.4 million for the nine months ended September 30, 2012, compared to the same period in 2011, primarily due to $212.5 million, net of issuance costs, received from the sale of our common stock to an affiliate of GSK.

Off Balance-Sheet Arrangements

We lease various real properties under an operating lease that generally requires us to pay taxes, insurance, maintenance, and minimum lease payments. This lease has options to renew.

We have not entered into any off-balance sheet financial arrangements and have not established any structured finance or special purpose entities. We have not guaranteed any debts or commitments of other entities or entered into any options on non-financial assets.

Contractual Obligations and Commercial Commitments

During the first nine months of 2012, there have been no significant changes in our payments due under contractual obligations, compared to those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2011, except that we entered into a series of purchase agreements with Astellas for the purchase of VIBATIV® active pharmaceutical ingredient and other raw materials of up to $6.2 million and VIBATIV® finished goods inventory of up to $4.2 million, which inventory remains subject to release. As of September 30, 2012, we had purchased $4.3 million of active pharmaceutical ingredient and other raw materials pursuant to these purchase agreements.

We indemnify our officers and directors for certain events or occurrences, subject to certain limits. We may be subject to contingencies that may arise from matters such as product liability claims, legal proceedings, shareholder suits and tax matters, as such, we are unable to estimate the potential exposure related to these indemnification agreements. We have not recognized any liabilities relating to these agreements as of September 30, 2012.

Pursuant to our LABA collaboration with GSK, we will be obligated to make milestone payments to GSK which could total as much as $220.0 million if both a single-agent and a combination product or two different combination products containing the LABA VI are launched in multiple regions of the world. These potential milestone payments could be payable to GSK within the next two years. We have not recognized any liabilities relating to this agreement as of September 30, 2012.

Item 3. Quantitative and Qualitative Disclosure About Market Risk

During the first nine months of 2012, there have been no significant changes in our market risk or how our market risk is managed, compared to those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2011.

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Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures.

We conducted an evaluation as of September 30, 2012, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, which are defined under SEC rules as controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files under the Securities Exchange Act of 1934 (Exchange Act) is recorded, processed, summarized and reported within required time periods. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective.

Limitations on the Effectiveness of Controls

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefit of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within Theravance have been detected. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) identified in connection with the evaluation required by paragraph (d) of Rule 13a-15 of the Exchange Act, which occurred during our most recent fiscal quarter which has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

Risks Related to our Business

Item 1A. Risk Factors

In addition to the other information in this Quarterly Report on Form 10-Q, the following risk factors should be considered carefully in evaluating our business and us.

Risks Related to our Business

If regulatory authorities determine that the Phase 3 programs for FF/VI in asthma and/or chronic obstructive pulmonary disease (COPD) do not demonstrate adequate safety and efficacy, the continued development of FF/VI may be significantly delayed, it may not be approved by regulatory authorities, and even if approved it may be subject to restrictive labeling, any of which will harm our business, and the price of our securities could fall.

During the first quarter of 2012, we announced the completion of, and reported certain top-line data from, the Phase 3 registrational program for FF/VI in COPD and asthma. In July 2012, GSK submitted regulatory applications for FF/VI (proposed brand name Relvar™) in Europe for both COPD and asthma, and for FF/VI (proposed brand name Breo™) in the U.S. for COPD and both submissions have been accepted for review. In September 2012, GSK announced that it was commencing an additional Phase 3 study to complete the U.S. asthma filing package. The Phase 3b program for FF/VI in COPD commenced in February 2011. Any adverse developments or results or perceived adverse developments or results with respect to the FF/VI regulatory submissions, the asthma Phase 3 study or the Phase 3b program will significantly harm our business and could cause the price of our securities to fall. Examples of such adverse developments include, but are not limited to:

- not every study in the Phase 3 programs for FF/VI achieved its primary endpoint, and the FDA and/or other regulatory authorities may determine that additional clinical studies are required;
- inability to gain, or delay in gaining, regulatory approval for the new Ellipta™ delivery device used in these programs;
- safety, efficacy or other concerns arising from clinical or non-clinical studies in these programs. For example, GSK is investigating reports of fatal pneumonia with FF/VI primarily at the highest dose, and the large Phase 3b program in COPD is ongoing;

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- safety, efficacy or other concerns arising from clinical or non-clinical studies with umeclidinium bromide/vilanterol (UMEC/VI) having to do with the LABA VI, which is also a component of FF/VI;
- regulatory authorities determining that the Phase 3 program in asthma or COPD raises safety concerns or does not demonstrate adequate efficacy; or
- any change in FDA policy or guidance regarding the use of LABAs to treat asthma.

On February 18, 2010, the FDA announced that LABAs should not be used alone in the treatment of asthma and will require manufacturers to include this warning in the product labels of these drugs, along with taking other steps to reduce the overall use of these medicines. The FDA now requires that the product labels for LABA medicines reflect, among other things, that the use of LABAs is contraindicated without the use of an asthma controller medication such as an inhaled corticosteroid, that LABAs should only be used long-term in patients whose asthma cannot be adequately controlled on asthma controller medications, and that LABAs should be used for the shortest duration of time required to achieve control of asthma symptoms and discontinued, if possible, once asthma control is achieved. In addition, on March 10 and 11, 2010, the FDA held an Advisory Committee to discuss the design of medical research studies (known as “clinical trial design”) to evaluate serious asthma outcomes (such as hospitalizations, a procedure using a breathing tube known as intubation, or death) with the use of LABAs in the treatment of asthma in adults, adolescents, and children. Further, in April 2011, the FDA announced that to further evaluate the safety of LABAs, it is requiring the manufacturers of currently marketed LABAs to conduct additional randomized, double-blind, controlled clinical trials comparing the addition of LABAs to inhaled corticosteroids versus inhaled corticosteroids alone. Results from these post-marketing studies are expected in 2017. It is unknown at this time what, if any, effect these or future FDA actions will have on the prospects for FF/VI. The current uncertainty regarding the FDA’s position on LABAs for the treatment of asthma and the lack of consensus expressed at the March 2010 Advisory Committee may result in the FDA requiring additional asthma clinical trials in the United States for FF/VI and increase the overall risk for FF/VI for the treatment of asthma in the United States.

If regulatory authorities determine that the Phase 3 program for UMEC/VI for the treatment of COPD does not demonstrate adequate safety and efficacy, continued development of UMEC/VI will be significantly delayed or terminated, our business will be harmed, and the price of our securities could fall.

The Phase 3 program for UMEC/VI with the combination of a LAMA umeclidinium bromide (UMEC), and a LABA, VI, for the treatment of COPD commenced in February 2011. In July 2012, GSK and we reported top-line results from four pivotal studies in this Phase 3 program and in August 2012, GSK and we announced the completion of this Phase 3 program and reported certain top-line data from the remaining studies in the registrational program. GSK plans to commence global regulatory submissions for UMEC/VI from the end of 2012. Any adverse developments or results or perceived adverse developments or results with respect to the UMEC/VI program will significantly harm our business and could cause the price of our securities to fall. Examples of such adverse developments include, but are not limited to:

- the FDA and/or other regulatory authorities determining that additional clinical studies are required with respect to the Phase 3 program in COPD;
- inability to gain, or delay in gaining, regulatory approval for the new Ellipta™ delivery device used in the program;
- safety, efficacy or other concerns arising from clinical or non-clinical studies in this program;
- safety, efficacy or other concerns arising from clinical or non-clinical studies with FF/VI having to do with the LABA, VI, which is also a component of UMEC/VI;
- regulatory authorities determining that the Phase 3 program in COPD raises safety concerns or does not demonstrate adequate efficacy; or

- any change in FDA policy or guidance regarding the use of LABAs combined with a LAMA to treat COPD.

If the MABA program for the treatment of COPD does not demonstrate safety and efficacy, the MABA program will be significantly delayed or terminated, our business will be harmed, and the price of our securities could fall.

The lead compound, GSK961081 ('081), in the bifunctional muscarinic antagonist-beta$_2$ agonist (MABA) program with GSK has completed a Phase 2b study and a Phase 1 study in combination with fluticasone propionate (FP), an inhaled corticosteroid (ICS), and there are a number of Phase 3-enabling non-clinical studies. The results from the Phase 2b COPD study and a number of non-clinical studies will inform the most appropriate dose and dosing interval for '081 and progression to Phase 3. Any adverse developments or

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results or perceived adverse developments or results with respect to these studies will harm our business and could cause the price of our securities to fall. Examples of such adverse developments include, but are not limited to:

- the FDA and/or other regulatory authorities determining that any of these studies do not demonstrate adequate safety or efficacy, or that additional non-clinical or clinical studies are required with respect to the MABA program;
- inability to gain, or delay in gaining, regulatory approval for the delivery device used in the program;
- safety, efficacy or other concerns arising from clinical or non-clinical studies in this program; or
- any change in FDA policy or guidance regarding the use of MABAs to treat COPD.

If telavancin receives an unfavorable outcome at the FDA's Anti-Infective Drugs Advisory Committee in November 2012 or if it is not approved for nosocomial pneumonia (NP) in the United States, the commercialization of VIBATIV® in the U.S. will continue to be adversely affected and the price of our securities could fall.

Our first New Drug Application (NDA), for VIBATIV® (telavancin) for the treatment of complicated skin and skin structure infections (cSSSI) caused by susceptible Gram-positive bacteria in adult patients, was approved by the FDA in September 2009. In January 2009, we submitted a second telavancin NDA to the FDA for the NP indication based on data from our two Phase 3 studies referred to as the ATTAIN studies. These studies were conducted in accordance with the then current draft FDA guidelines and met their primary efficacy endpoint of clinical cure. During the fourth quarter of 2010 the FDA issued new draft guidance for antibacterial clinical trial design for the treatment of NP with a focus on mortality as the primary efficacy endpoint. In late 2010, we received a Complete Response Letter from the FDA indicating that the ATTAIN studies do not meet the new draft guidance and that additional clinical studies will be required for approval. We do not plan to conduct additional clinical studies for NP, but we do intend to continue to engage with the FDA concerning the NP NDA. In September 2012, we received notice that the FDA's Anti-Infective Drugs Advisory Committee ("AIDAC") plans to discuss the NP NDA for VIBATIV® at a meeting on November 29, 2012. Any adverse developments or perceived adverse developments with respect to our NP NDA or the AIDAC meeting could adversely affect the prospects of VIBATIV® and could cause the price of our securities to fall. Lack of FDA approval for use of telavancin to treat NP has adversely affected and may continue to adversely affect commercialization of this medicine in the United States.

Our collaboration agreement for VIBATIV® was terminated in early 2012, VIBATIV® was returned to us, and we have no experience selling or distributing products and no internal capability to do so.

Generally, our strategy is to engage pharmaceutical or other healthcare companies with an existing sales and marketing organization and distribution system to market, sell and distribute our products. We may not be able to establish these sales and distribution relationships on acceptable terms, or at all. With VIBATIV®, which was returned to us by Astellas in January 2012, and any of our product candidates that receive regulatory approval in the future and are not covered by our current agreements with GSK or another sales and distribution partner, we will need a partner in order to commercialize such products unless we establish an internal sales and marketing organization with appropriate technical expertise and supporting infrastructure and distribution capability. At present, we have no sales personnel and a limited number of marketing personnel. Factors that may inhibit our efforts to commercialize our products without strategic partners or licensees include:

- significant costs and expenses associated with creating an independent sales and marketing organization with appropriate technical expertise and supporting infrastructure and distribution capability;
- our unproven ability to recruit and retain adequate numbers of effective sales and marketing personnel;
- the unproven ability of sales personnel to obtain access to or persuade adequate numbers of physicians to prescribe our products; and
- the lack of complementary products to be offered by sales personnel, which may put us at a competitive disadvantage relative to companies with more extensive product lines.

If we are not able to partner with a third party with marketing, sales and distribution capabilities and are not successful in recruiting sales and marketing personnel or in building an internal sales and marketing organization with appropriate technical expertise and supporting infrastructure and distribution capability, we will have difficulty commercializing VIBATIV® and other

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product candidates, which would adversely affect our business and financial condition and which could cause the price of our securities to fall.

With regard to all of our programs, any delay in commencing or completing clinical studies for product candidates and any adverse results from clinical or non-clinical studies or regulatory obstacles product candidates may face, would harm our business and could cause the price of our securities to fall.

Each of our product candidates must undergo extensive non-clinical and clinical studies as a condition to regulatory approval. Non-clinical and clinical studies are expensive, take many years to complete and study results may lead to delays in further studies or decisions to terminate programs. For example, we had planned to commence the Phase 2b study in our MABA program with GSK in 2009, but the program was delayed until late 2010.

The commencement and completion of clinical studies for our product candidates may be delayed and programs may be terminated due to many factors, including, but not limited to:

- lack of effectiveness of product candidates during clinical studies;
- adverse events, safety issues or side effects relating to the product candidates or their formulation into medicines;
- inability to raise additional capital in sufficient amounts to continue our development programs, which are very expensive;
- the need to sequence clinical studies as opposed to conducting them concomitantly in order to conserve resources;
- our inability to enter into partnering arrangements relating to the development and commercialization of our programs and product candidates;
- our inability or the inability of our collaborators or licensees to manufacture or obtain from third parties materials sufficient for use in non-clinical and clinical studies;
- governmental or regulatory delays and changes in regulatory requirements, policy and guidelines;
- failure of our partners to advance our product candidates through clinical development;
- delays in patient enrollment and variability in the number and types of patients available for clinical studies;
- difficulty in maintaining contact with patients after treatment, resulting in incomplete data;
- varying regulatory requirements or interpretations of data among the FDA and foreign regulatory authorities; and
- a regional disturbance where we or our collaborative partners are enrolling patients in clinical trials, such as a pandemic, terrorist activities or war, political unrest or a natural disaster.

If our product candidates that we develop on our own or through collaborative partners are not approved by regulatory authorities, including the FDA, we will be unable to commercialize them.

The FDA must approve any new medicine before it can be marketed and sold in the United States. We must provide the FDA and similar foreign regulatory authorities with data from preclinical and clinical studies that demonstrate that our product candidates are safe and effective for a defined indication before they can be approved for commercial distribution. We will not obtain this approval for a product candidate unless and until the FDA approves a NDA. The processes by which regulatory approvals are obtained from the FDA to market and sell a new product are complex, require a number of years and involve the expenditure of substantial resources. In order to market our medicines in foreign jurisdictions, we must obtain separate regulatory approvals in each country. The approval procedure varies among countries and can involve additional testing, and the time required to obtain approval may differ from that required to obtain FDA approval. Approval by the FDA does not ensure approval by regulatory authorities in other countries, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. Conversely, failure to obtain approval in one or more jurisdictions may make approval in other jurisdictions more difficult.

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Clinical studies involving our product candidates may reveal that those candidates are ineffective, inferior to existing approved medicines, unacceptably toxic, or that they have other unacceptable side effects. In addition, the results of preclinical studies do not necessarily predict clinical success, and larger and later-stage clinical studies may not produce the same results as earlier-stage clinical studies.

Frequently, product candidates that have shown promising results in early preclinical or clinical studies have subsequently suffered significant setbacks or failed in later clinical or non-clinical studies. In addition, clinical and non-clinical studies of potential products often reveal that it is not possible or practical to continue development efforts for these product candidates. If these studies are substantially delayed or fail to prove the safety and effectiveness of our product candidates in development, we may not receive regulatory approval of any of these product candidates and our business and financial condition will be materially harmed and the price of our securities may fall.

If any product candidates, in particular those in any respiratory program with GSK, are determined to be unsafe or ineffective in humans, our business will be adversely affected and the price of our securities could fall.

Although our first product, VIBATIV®, is approved in the U.S. and Canada, none of our other product candidates have been approved by regulatory authorities. We are uncertain whether any of our other product candidates and our collaborative partner's product candidates will prove effective and safe in humans or meet applicable regulatory standards. In addition, our approach to applying our expertise in multivalency to drug discovery may not result in the creation of successful medicines. The risk of failure for our product candidates is high. For example, in late 2005, we discontinued our overactive bladder program based upon the results of our Phase 1 studies with compound TD-6301, and GSK discontinued development of TD-5742, the first LAMA compound licensed from us, after completing a single-dose Phase 1 study. The data supporting our drug discovery and development programs is derived solely from laboratory experiments, non-clinical studies and clinical studies. A number of other compounds remain in the lead identification, lead optimization, preclinical testing or early clinical testing stages.

Several well-publicized Complete Response letters issued by the FDA and safety-related product withdrawals, suspensions, post-approval labeling revisions to include boxed warnings and changes in approved indications over the last several years, as well as growing public and governmental scrutiny of safety issues, have created an increasingly conservative regulatory environment. The implementation of new laws and regulations, and revisions to FDA clinical trial design guidance, have increased uncertainty regarding the approvability of a new drug. Further, there are additional requirements for approval of new drugs, including advisory committee meetings for new chemical entities, and formal risk evaluation and mitigation strategy (REMS) at the FDA's discretion. These laws, regulations, additional requirements and changes in interpretation could cause non-approval or further delays in the FDA's review and approval of our and our collaborative partner's product candidates.

There currently is no reliable manufacturer for VIBATIV® drug product supply and we rely on a single source of supply for a number of our product candidates; accordingly, our business will be harmed if a reliable alternate source of VIBATIV® drug product is not qualified and engaged on a timely basis or the single-source manufacturers are not able to satisfy demand and alternative sources are not available.

During the fourth quarter of 2011, the third party manufacturer of VIBATIV® drug product notified the FDA of an ongoing investigation related to its production equipment and processes. The notification included all products manufactured at the third party manufacturer's facility which remain within expiry, including batches of manufactured but unreleased VIBATIV®. In November 2011, Astellas (our former VIBATIV® collaboration partner) voluntarily placed a hold on distribution of VIBATIV® to wholesalers, and cancelled pending orders for VIBATIV® with this manufacturer. VIBATIV® drug product previously manufactured by this manufacturer will not become available for sale in the U.S. unless and until the batches are released. Similarly, our purchase orders for this inventory cannot be fulfilled unless and until the batches are released. We cannot predict when or if the manufactured batches of VIBATIV® will be released. In addition, in August 2011 the third party manufacturer of VIBATIV® drug product announced its intention to transition out of the contract manufacturing services business over the next several years. Additional VIBATIV® drug product will need to be manufactured to meet longer-term U.S. demand as well as demand from the E.U. and Canada. In May 2012 the European Commission suspended marketing authorization for VIBATIV® because the single-source VIBATIV® drug product supplier did not meet the good manufacturing practice (GMP) requirements for the manufacture of VIBATIV®. No VIBATIV® drug product intended to meet E.U. specifications has as yet been manufactured.

If the VIBATIV® drug product manufactured by this third party manufacturer is not released in the near future, the commercialization of VIBATIV® in the U.S. will continue to be adversely affected, and if supplemental or alternative commercial manufacture of VIBATIV® drug product cannot be arranged on a timely basis, the commercial introduction of VIBATIV® in the E.U. and Canada will be further delayed. In each such case, our business will be harmed and the price of our securities could fall. In May 2012, we entered into a Technology Transfer and Supply Agreement with Hospira Worldwide, Inc. (Hospira) and technology

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transfer activities are in process. We must obtain regulatory approval for VIBATIV® drug product that will be manufactured at Hospira's facility before any such product may be sold, and this regulatory approval process could extend through mid-2013.

We have a single source of supply of telavancin API. If, for any reason, the single-source third party manufacturer of telavancin API is unable or unwilling to perform, or if its performance does not meet regulatory requirements, including maintaining GMP compliance, we may not be able to locate alternative manufacturers, enter into acceptable agreements with them or obtain sufficient quantities of API in a timely manner. Any inability to acquire sufficient quantities of API in a timely manner from current or future sources could further adversely affect the commercialization of VIBATIV® and could cause the price of our securities to fall.

With respect to our programs other than VIBATIV®, we have limited in-house production capabilities for non-clinical and early clinical study purposes, and depend primarily on a number of third-party API and drug product manufacturers. We may not have long-term agreements with these third parties and our agreements with these parties may be terminable at will by either party at any time. If, for any reason, these third parties are unable or unwilling to perform, or if their performance does not meet regulatory requirements, we may not be able to locate alternative manufacturers or enter into acceptable agreements with them. Any inability to acquire sufficient quantities of API and drug product in a timely manner from these third parties could delay clinical studies, prevent us from developing our product candidates in a cost-effective manner or on a timely basis. In addition, manufacturers of our API and drug product are subject to the FDA's cGMP regulations and similar foreign standards and we do not have control over compliance with these regulations by our manufacturers.

Our manufacturing strategy presents the following additional risks:

- because of the complex nature of our compounds, our manufacturers may not be able to successfully manufacture our APIs and/or drug products in a cost effective and/or timely manner and changing manufacturers for our APIs or drug products could involve lengthy technology transfer, validation and regulatory qualification activities for the new manufacturer. For example, we are in the process of transitioning to a new drug product manufacturer for VIBATIV®, and delays in technology transfer, validation and regulatory qualification activities could be encountered;

- the processes required to manufacture certain of our APIs and drug products are specialized and available only from a limited number of third-party manufacturers;

- some of the manufacturing processes for our APIs and drug products have not been scaled to quantities needed for continued clinical studies or commercial sales, and delays in scale-up to commercial quantities could delay clinical studies, regulatory submissions and commercialization of our product candidates; and

- because some of the third-party manufacturers are located outside of the U.S., there may be difficulties in importing our APIs and drug products or their components into the U.S. as a result of, among other things, FDA import inspections, incomplete or inaccurate import documentation or defective packaging.

Even if our product candidates receive regulatory approval, as VIBATIV® has, commercialization of such products may be adversely affected by regulatory actions and oversight.

Even if we receive regulatory approval for our product candidates, this approval may include limitations on the indicated uses for which we can market our medicines or the patient population that may utilize our medicines, which may limit the market for our medicines or put us at a competitive

disadvantage relative to alternative therapies. For example, VIBATIV®'s U.S. labeling contains a boxed warning regarding the risks of use of VIBATIV® during pregnancy. Products with boxed warnings are subject to more restrictive advertising regulations than products without such warnings. In addition, the VIBATIV® labeling that was approved for the E.U. in 2011 specifies that VIBATIV® should be used only in situations where it is known or suspected that other alternatives are not suitable. These restrictions could make it more difficult to market VIBATIV®. In May 2012 the European Commission suspended marketing authorization for VIBATIV® because the single-source VIBATIV® drug product supplier did not meet the GMP requirements for the manufacture of VIBATIV®. With VIBATIV® approved in certain countries, we are subject to continuing regulatory obligations, such as safety reporting requirements and additional post-marketing obligations, including regulatory oversight of promotion and marketing.

In addition, the manufacturing, labeling, packaging, adverse event reporting, advertising, promotion and recordkeeping for the approved product remain subject to extensive and ongoing regulatory requirements. If we become aware of previously unknown problems with an approved product in the U.S. or overseas or at contract manufacturers' facilities, a regulatory authority may impose restrictions on the product, the contract manufacturers or on us, including requiring us to reformulate the product, conduct additional clinical studies, change the labeling of the product, withdraw the product from the market or require the contract manufacturer to implement changes to its facilities. For example, during the fourth quarter of 2011, the third party manufacturer of VIBATIV® drug product notified the FDA of an ongoing investigation related to its production equipment and processes. The notification included all

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products manufactured at the third party manufacturer's facility which remain within expiry, including batches of manufactured but unreleased VIBATIV®. Astellas (our former VIBATIV® collaboration partner) subsequently placed a voluntary hold on distribution of VIBATIV® to wholesalers and cancelled pending orders for VIBATIV® with this manufacturer. With this supply interruption and the termination of our VIBATIV® collaboration agreement with Astellas, commercialization of VIBATIV® has essentially stopped, we have experienced a significant drop in the sales of the product and the reputation of VIBATIV® in the marketplace will likely suffer.

We are also subject to regulation by regional, national, state and local agencies, including the Department of Justice, the Federal Trade Commission, the Office of Inspector General of the U.S. Department of Health and Human Services and other regulatory bodies with respect to VIBATIV®, as well as governmental authorities in those foreign countries in which any of our product candidates are approved for commercialization. The Federal Food, Drug, and Cosmetic Act, the Public Health Service Act and other federal and state statutes and regulations govern to varying degrees the research, development, manufacturing and commercial activities relating to prescription pharmaceutical products, including non-clinical and clinical testing, approval, production, labeling, sale, distribution, import, export, post-market surveillance, advertising, dissemination of information and promotion. If we or any third parties that provide these services for us are unable to comply, we may be subject to regulatory or civil actions or penalties that could significantly and adversely affect our business. Any failure to maintain regulatory approval will limit our ability to commercialize our product candidates, which would materially and adversely affect our business and financial condition, which may cause our stock price to decline.

We have incurred operating losses in each year since our inception and expect to continue to incur substantial losses for the foreseeable future.

We have been engaged in discovering and developing compounds and product candidates since mid-1997. Our first approved product, VIBATIV®, was launched by our former partner Astellas in the U.S. in November 2009, and to date we have received only modest revenues from VIBATIV® sales. We may never generate sufficient revenue from the sale of medicines or royalties on sales by our partners to achieve profitability. As of September 30, 2012, we had an accumulated deficit of approximately $1.3 billion.

We expect to incur substantial expenses as we continue our drug discovery and development efforts, particularly to the extent we advance our product candidates into and through clinical studies, which are very expensive. For example, in July 2012, we announced positive results from the key study in our Phase 2b program with TD-1211 in our Peripheral Mu Opioid Receptor Antagonist program for opioid-induced constipation. Though we seek to partner this program, we may choose to progress TD-1211 into Phase 3 studies by ourselves, which would increase our operating expenses substantially. As a result, we expect to continue to incur substantial losses for the foreseeable future. We are uncertain when or if we will be able to achieve or sustain profitability. Failure to become and remain profitable would adversely affect the price of our securities and our ability to raise capital and continue operations.

If we fail to obtain the capital necessary to fund our operations, we may be unable to develop our product candidates or commercialize VIBATIV® and we could be forced to share our rights to commercialize our product candidates with third parties on terms that may not be favorable to us.

We need large amounts of capital to support our research and development efforts. If we are unable to secure capital to fund our operations we will not be able to continue our discovery and development efforts and we might have to enter into strategic collaborations that could require us to share commercial rights to our medicines to a greater extent than we currently intend. Based on our current operating plans, milestone and royalty forecasts and spending assumptions, we believe that our cash and cash equivalents and marketable securities will be sufficient to meet our anticipated operating needs for at least the next twelve months. If our current operating plans, milestone and royalty forecasts or spending assumptions change, we may seek additional funding sooner in the form of public or private equity offerings or debt financings. For example, if we chose to conduct Phase 3 studies with TD-1211 in our Peripheral Mu Opioid Receptor Antagonist program for opioid-induced constipation by ourselves or if we were to build the sales and marketing, distribution and compliance infrastructure to commercialize VIBATIV® without additional partners, our capital needs would increase substantially. In addition, we initiated a Phase 2 study with TD-9855 in the MARIN program in late 2011 and we are planning a second Phase 2 study with TD-9855. We also intend to invest in other assets in our pipeline, including programs in earlier-stage clinical development and late-stage discovery. Further, in connection with the January 2012 termination of our collaboration agreement with Astellas, we entered into purchase agreements for VIBATIV® active pharmaceutical ingredient and raw materials of up to $6.2 million and VIBATIV® finished goods inventory of up to $4.2 million, which is subject to release of the inventory by a third party manufacturer. As of September 30, 2012, we had purchased $4.3 million of active pharmaceutical ingredient and raw materials pursuant to these purchase agreements. In addition, under our LABA collaboration with GSK, in the event that a product containing vilanterol (VI), which is the LABA product candidate in FF/VI and UMEC/VI and which was discovered by GSK, is approved and launched in multiple regions of the world as both a single-agent and a combination product or two different combination products, we will be obligated to pay GSK milestone payments that could total as much as $220.0 million and we will not be entitled

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to receive any further milestone payments from GSK. Future financing to meet our capital needs may not be available in sufficient amounts or on terms acceptable to us, if at all. Even if we are able to raise additional capital, such financing may result in significant dilution to existing security holders. If we are unable to raise additional capital in sufficient amounts or on terms acceptable to us, we may have to make reductions in our workforce and may be prevented from continuing our discovery and development efforts and exploiting other corporate opportunities. This could harm our business, prospects and financial condition and cause the price of our securities to fall.

VIBATIV® may not be accepted by physicians, patients, third party payors, or the medical community in general, and this risk is aggravated by the current critical product shortages and regional supply outages and the suspension of marketing authorization in the European Union.

The commercial success of VIBATIV® depends upon its acceptance by physicians, patients, third party payors and the medical community in general. We cannot be sure that VIBATIV® will be accepted by these parties. VIBATIV® competes with vancomycin, a relatively inexpensive generic drug that is manufactured by a variety of companies, and a number of existing antibacterials manufactured and marketed by major pharmaceutical companies and others, and may compete against new antibacterials that are not yet on the market. Even if the medical community accepts that VIBATIV® is safe and efficacious for its indicated use, physicians may restrict the use of VIBATIV® due to the current product shortages stemming from the manufacturing issues at the drug product supplier, the January 2012 termination of our VIBATIV® collaboration agreement with Astellas, or otherwise. If we are unable to demonstrate to physicians that, based on experience, clinical data, side-effect profiles and other factors, VIBATIV® is preferable to vancomycin and other antibacterial drugs, we may never generate meaningful revenue from VIBATIV® which could cause the price of our securities to fall. The degree of market acceptance of VIBATIV® depends on a number of factors, including, but not limited to:

- the demonstration of the clinical efficacy and safety of VIBATIV®;
- the experiences of physicians, patients and payors with the use of VIBATIV® in the U.S.;
- potential negative perceptions of physicians related to our inability to obtain FDA approval of our NP NDA, the product shortages and regional supply outages stemming from the manufacturing issues at the drug product supplier or the termination of our VIBATIV® collaboration agreement with Astellas in January 2012;
- potential negative perceptions of physicians related to the European Commission's suspension of marketing authorization for VIBATIV® because the single-source VIBATIV® drug product supplier did not meet the GMP requirements for the manufacture of VIBATIV®;
- the advantages and disadvantages of VIBATIV® compared to alternative therapies;
- our ability to educate the medical community about the safety and effectiveness of VIBATIV®;
- the reimbursement policies of government and third party payors; and
- the market price of VIBATIV® relative to competing therapies.

If our partners do not satisfy their obligations under our agreements with them, or if they terminate our partnerships with them, as Astellas did with our VIBATIV® collaboration agreement in January 2012, we may not be able to develop or commercialize our partnered product candidates as planned.

We entered into our LABA collaboration agreement with GSK in November 2002, our strategic alliance agreement with GSK in March 2004, and our VIBATIV® collaboration agreement with Astellas in November 2005. In October 2012, we entered into an exclusive development and commercialization agreement with Alfa Wassermann for TD-5108, our lead compound in the 5-HT_4 program, covering the EU, Russia, China, Mexico and certain other countries, and we entered into a research collaboration and license agreement with Merck to discover, develop and commercialize novel small molecule therapeutics for the treatment of cardiovascular disease on an exclusive, worldwide basis. In connection with these agreements, we have granted to these parties certain rights regarding the use of our patents and technology with respect to compounds in our development programs, including development and marketing rights. Under our GSK agreements, GSK has full responsibility for development and commercialization of FF/VI, UMEC/VI and any product candidates in the MABA program. Any future milestone payments or royalties to us from these programs will depend on the extent to which GSK advances the product candidate through development and, if approved, commercialization. Astellas terminated the VIBATIV® agreement in January 2012. The Merck and Alfa Wassermann agreements provide us with

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research and development funding, respectively, for the programs under license, and if either partner decides not to progress the licensed program, we may not be able to develop or commercialize the program on our own.

Our partners might not fulfill all of their obligations under these agreements, and, in certain circumstances, they may terminate our partnership with them, as Astellas did in January 2012. In either event, we may be unable to assume the development and commercialization of the product candidates covered by the agreements or enter into alternative arrangements with a third party to develop and commercialize such product candidates. If a partner elected to promote its own products and product candidates in preference to those licensed from us, future payments to us could be reduced and our business and financial condition would be materially and adversely affected. Accordingly, our ability to receive any revenue from the product candidates covered by these agreements is dependent on the efforts of the partner. We could also become involved in disputes with a partner, which could lead to delays in or termination of our development and commercialization programs and time-consuming and expensive litigation or arbitration.

If a partner terminates or breaches its agreements with us, or otherwise fails to complete its obligations in a timely manner, the chances of successfully developing or commercializing product candidates under the collaboration could be materially and adversely affected. For example, Astellas terminated the VIBATIV® collaboration agreement in January 2012, and due to the termination, current product shortages, regional supply outages and suspension of marketing authorization in the European Union stemming from the manufacturing issues at the third party VIBATIV® drug product supplier, the commercialization of VIBATIV® in the U.S. has essentially stopped and the commercial introduction of VIBATIV® in the E.U. and Canada has been delayed.

If we are unable to enter into future collaboration arrangements or if any such collaborations with third parties are unsuccessful, we will be unable to fully develop and commercialize VIBATIV® and our product candidates and our business will be adversely affected.

We have active collaborations with GSK for FF/VI, UMEC/VI and the MABA program, with Alfa Wassermann for TD-5108, with Merck for novel small molecule therapeutics for the treatment of cardiovascular disease, and with R-Pharm CJSC for TD-1792, our investigational antibiotic, and telavancin. Additional collaborations will be needed to fund later-stage development of our product candidates that have not been licensed to a collaborator or for territory that is not covered by the collaboration, and to commercialize these product candidates if approved by the necessary regulatory authorities. Each of TD-5108, our lead compound in the 5-HT_4 program, TD-1792, our investigational antibiotic and TD-4208, our LAMA compound, has successfully completed a Phase 2 proof-of-concept study, and we recently reported positive results from a Phase 2b study with TD-1211, the lead compound in our Peripheral Mu Opioid Receptor Antagonist program for opioid-induced constipation. In addition, in connection with the expansion of the MABA program under the strategic alliance with GSK in October 2011, GSK relinquished its right to option our MARIN and ARNI programs. Also, we now have full rights to VIBATIV® as a result of the termination of our collaboration agreement with Astellas in January 2012. We currently intend to seek additional third parties with which to pursue collaboration arrangements for the development and commercialization of our development programs and for the future commercialization of VIBATIV®. Collaborations with third parties regarding these programs or our other programs may require us to relinquish material rights, including revenue from commercialization of our medicines, on terms that are less attractive than our current arrangements or to assume material ongoing development obligations that we would have to fund. These collaboration arrangements are complex and time-consuming to negotiate, and if we are unable to reach agreements with third-party collaborators, we may fail to meet our business objectives and our financial condition may be adversely affected. We face significant competition in seeking third-party collaborators, especially in the current uncertain economy, which is driving many biotechnology and biopharmaceutical companies to seek to sell or license their assets. We may be unable to find third parties to pursue product collaborations on a timely basis or on acceptable terms. Furthermore, for any collaboration, we may not be able to control the amount of time and resources that our partners devote to our product candidates and our partners may choose to pursue alternative products. Our inability to successfully collaborate with third parties would increase our development costs and would limit the likelihood of successful commercialization of our product candidates which may cause our stock price to decline.

We depend on third parties in the conduct of our clinical studies for our product candidates.

We depend on independent clinical investigators, contract research organizations and other third-party service providers in the conduct of our non-clinical and clinical studies for our product candidates. We rely heavily on these parties for execution of our non-clinical and clinical studies, and control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that our clinical studies are conducted in accordance with good clinical practices (GCPs) and other regulations as required by the FDA and foreign regulatory authorities, and the applicable protocol. Failure by these parties to comply with applicable regulations, GCPs and protocols in conducting studies of our product candidates can result in a delay in our development programs or non-approval of our product candidates by regulatory authorities.

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The FDA enforces good clinical practices and other regulations through periodic inspections of trial sponsors, clinical research organizations (CROs), principal investigators and trial sites. For example, in connection with the FDA's review of our telavancin NDAs, the FDA conducted inspections of Theravance and certain of our study sites, clinical investigators and CROs. If we or any of the third parties on which we have relied to conduct our clinical studies are determined to have failed to comply with GCPs, the study protocol or applicable regulations, the clinical data generated in our studies may be deemed unreliable. This could result in non-approval of our product candidates by the FDA, or we or the FDA may decide to conduct additional audits or require additional clinical studies, which would delay our development programs, could result in significant additional costs and could cause the price of our securities to fall.

We face substantial competition from companies with more resources and experience than we have, which may result in others discovering, developing, receiving approval for or commercializing products before or more successfully than we do.

Our ability to succeed in the future depends on our ability to demonstrate and maintain a competitive advantage with respect to our approach to the discovery and development of medicines. Our objective is to discover, develop and commercialize new small molecule medicines with superior efficacy, convenience, tolerability and/or safety. We expect that any medicines that we commercialize with our collaborative partners will compete with existing or future market-leading medicines.

Many of our potential competitors have substantially greater financial, technical and personnel resources than we have. In addition, many of these competitors have significantly greater commercial infrastructures than we have. Our ability to compete successfully will depend largely on our ability to leverage our experience in drug discovery and development to:

- discover and develop medicines that are superior to other products in the market;
- attract and retain qualified personnel;
- obtain patent and/or other proprietary protection for our medicines and technologies;
- obtain required regulatory approvals; and
- successfully collaborate with pharmaceutical companies in the discovery, development and commercialization of new medicines.

Established pharmaceutical companies may invest heavily to quickly discover and develop or in-license novel compounds that could make our product candidates obsolete. Accordingly, our competitors may succeed in obtaining patent protection, receiving FDA approval or discovering, developing and commercializing medicines before we do. Other companies are engaged in the discovery of medicines that would compete with the product candidates that we are developing.

Any new medicine that competes with a generic or proprietary market leading medicine must demonstrate compelling advantages in efficacy, convenience, tolerability and/or safety in order to overcome severe price competition and be commercially successful. VIBATIV® must demonstrate these advantages, as it competes with vancomycin, a relatively inexpensive generic drug that is manufactured by a number of companies, and a number of existing antibacterial drugs marketed by major and other pharmaceutical companies. If we are not able to compete effectively against our current and future competitors, our business will not grow, our financial condition and operations will suffer and the price of our securities could fall.

As the principles of multivalency become more widely known, we expect to face increasing competition from companies and other organizations that pursue the same or similar approaches. Novel therapies, such as gene therapy or effective vaccines for infectious diseases, may emerge that will make both conventional and multivalent medicine discovery efforts obsolete or less competitive.

If we lose key management or scientific personnel, or if we fail to retain our key employees, our ability to discover and develop our product candidates will be impaired.

We are highly dependent on principal members of our management team and scientific staff to operate our business. Our company is located in northern California, which is headquarters to many other biotechnology and biopharmaceutical companies and many academic and research institutions. As a result, competition for certain skilled personnel in our market remains intense. None of our employees have employment commitments for any fixed period of time and they all may leave our employment at will. If we fail to retain our qualified personnel or replace them when they leave, we may be unable to continue our development and commercialization activities, which may cause our stock price to decline.

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Our business and operations would suffer in the event of system failures.

Although we have security measures in place, our internal computer systems and those of our CROs and other service providers are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Any material system failure, accident or security breach could result in a material disruption to our business. For example, the loss of clinical trial data from completed or ongoing clinical trials of our product candidates could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. If a disruption or security breach results in a loss of or damage to our data or regulatory applications, or inadvertent disclosure of confidential or proprietary information, we could incur liability, the further development of our product candidates could be delayed and the price of our securities could fall.

Our principal facility is located near known earthquake fault zones, and the occurrence of an earthquake, extremist attack or other catastrophic disaster could cause damage to our facilities and equipment, which could require us to cease or curtail operations.

Our principal facility is located in the San Francisco Bay Area near known earthquake fault zones and therefore is vulnerable to damage from earthquakes. In October 1989, a major earthquake struck this area and caused significant property damage and a number of fatalities. We are also vulnerable to damage from other types of disasters, including power loss, attacks from extremist organizations, fire, floods, communications failures and similar events. If any disaster were to occur, our ability to operate our business could be seriously impaired. In addition, the unique nature of our research activities and of much of our equipment could make it difficult for us to recover from this type of disaster. We may not have adequate insurance to cover our losses resulting from disasters or other similar significant business interruptions and we do not plan to purchase additional insurance to cover such losses due to the cost of obtaining such coverage. Any significant losses that are not recoverable under our insurance policies could seriously impair our business and financial condition, which could cause the price of our securities to fall.

Risks Related to our Alliance with GSK

GSK's ownership of a significant percentage of our stock and its ability to acquire additional shares of our stock may create conflicts of interest, and may inhibit our management's ability to continue to operate our business in the manner in which it is currently being operated.

As of October 24, 2012, GSK beneficially owned approximately 26.7% of our outstanding capital stock, and GSK has the right to acquire stock from us to maintain its percentage ownership of our capital stock. GSK could have substantial influence in the election of our directors, delay or prevent a transaction in which stockholders might receive a premium over the prevailing market price for their shares and have significant control over certain changes in our business.

In addition, GSK may make an offer to our stockholders to acquire outstanding voting stock that would bring GSK's percentage ownership of our voting stock to no greater than 60%, provided that:

- the offer includes no condition as to financing;
- the offer is approved by a majority of our independent directors;
- the offer includes a condition that the holders of a majority of the shares of the voting stock not owned by GSK accept the offer by tendering their shares in the offer; and
- the shares purchased will be subject to the same provisions of the governance agreement as are the shares of voting stock currently held by GSK.

If pursuant to the provision described above GSK's ownership of us is greater than 50.1%, then *on or after* September 2, 2012, GSK is allowed to make an offer to our stockholders to acquire outstanding voting stock that would bring GSK's percentage ownership of our voting stock to 100%, provided that;

- the offer includes no condition as to financing;
- the offer is approved by a majority of our independent directors; and
- the offer includes a condition that the holders of a majority of the shares of the voting stock not owned by GSK accept the offer by tendering their shares in the offer.

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Further, pursuant to our certificate of incorporation, we renounce our interest in and waive any claim that a corporate or business opportunity taken by GSK constitutes a corporate opportunity of ours unless such corporate or business opportunity is expressly offered to one of our directors who is a director, officer or employee of GSK, primarily in his or her capacity as one of our directors.

GSK's significant ownership position and its rights under the governance agreement may deter or prevent efforts by other companies to acquire us, which could prevent our stockholders from realizing a control premium.

As of October 24, 2012, GSK beneficially owned approximately 26.7% of our outstanding capital stock. GSK may vote at its sole discretion on any proposal to effect a change of control of us or for us to issue equity securities to one or more parties that would result in that party or parties beneficially owning more than 20% of our outstanding capital stock. Our governance agreement with GSK requires us to exempt GSK from our stockholder rights plan, affords GSK certain rights to offer to acquire us in the event third parties seek to acquire our stock and contains other provisions that could deter or prevent another company from seeking to acquire us. For example, GSK may offer to acquire 100% of our outstanding stock from stockholders in certain circumstances, such as if we are faced with a hostile acquisition offer or if our board of directors acts in a manner to facilitate a change in control of us with a party other than GSK. As a result of GSK's significant ownership and its rights under the governance agreement, other companies may be less inclined to pursue an acquisition of us and therefore we may not have the opportunity to be acquired in a transaction that stockholders might otherwise deem favorable, including transactions in which our stockholders might realize a substantial premium for their shares.

GSK could sell or transfer a substantial number of shares of our common stock, which could depress the price of our securities or result in a change in control of our company.

Under our governance agreement with GSK, GSK could previously sell or transfer our common stock only pursuant to a public offering registered under the Securities Act or pursuant to Rule 144 of the Securities Act. Beginning in September 2012, GSK no longer has contractual restrictions on its ability to sell or transfer our common stock on the open market, in privately negotiated transactions or otherwise, and these sales or transfers could create substantial declines in the price of our securities or, if these sales or transfers were made to a single buyer or group of buyers, could contribute to a transfer of control of our company to a third party.

Risks Related to Legal and Regulatory Uncertainty

If our efforts to protect the proprietary nature of the intellectual property related to our technologies are not adequate, we may not be able to compete effectively in our market.

We rely upon a combination of patents, patent applications, trade secret protection and confidentiality agreements to protect the intellectual property related to our technologies. Any involuntary disclosure to or misappropriation by third parties of this proprietary information could enable competitors to quickly duplicate or surpass our technological achievements, thus eroding our competitive position in our market. The status of patents in the biotechnology and pharmaceutical field involves complex legal and scientific questions and is very uncertain. As of September 30, 2012, we owned 315 issued United States patents and 983 granted foreign patents, as well as additional pending United States and foreign patent applications. Our patent applications may be challenged or fail to result in issued patents and our existing or future patents may be invalidated or be too narrow to prevent third parties from developing or designing around these patents. If the sufficiency of the breadth or strength of protection provided by our patents with respect to a product candidate is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, the product candidate. Further, if we encounter delays in our clinical trials or in obtaining regulatory approval of our product candidates, the patent lives of the related product candidates would be reduced.

In addition, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, for processes for which patents are difficult to enforce and for any other elements of our drug discovery and development processes that involve proprietary know-how, information and technology that is not covered by patent applications. Although we require our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information and technology to enter into confidentiality agreements, we cannot be certain that this know-how, information and technology will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Further, the laws of some foreign countries do not protect proprietary rights to the same extent as the laws of the United States. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the United States and abroad. If we are unable to prevent material disclosure of the intellectual property related to our technologies to third parties, we will not be able to establish or, if established, maintain a competitive advantage in our market, which could materially adversely affect our business, financial condition and results of operations, which could cause the price of our securities to fall.

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Litigation or third-party claims of intellectual property infringement would require us to divert resources and may prevent or delay our drug discovery and development efforts.

Our commercial success depends in part on us and our partners not infringing the patents and proprietary rights of third parties. Third parties may assert that we or our partners are using their proprietary rights without authorization. There are third party patents that may cover materials or methods for treatment related to our product candidates. At present, we are not aware of any patent claims with merit that would adversely and materially affect our ability to develop our product candidates, but nevertheless the possibility of third party allegations cannot be ruled out. In addition, third parties may obtain patents in the future and claim that use of our technologies infringes upon these patents. Furthermore, parties making claims against us or our partners may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business.

In the event of a successful claim of infringement against us, we may have to pay substantial damages, obtain one or more licenses from third parties or pay royalties. In addition, even in the absence of litigation, we may need to obtain licenses from third parties to advance our research or allow commercialization of our product candidates, and we have done so from time to time. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further develop and commercialize one or more of our product candidates, which could harm our business significantly. In addition, in the future we could be required to initiate litigation to enforce our proprietary rights against infringement by third

parties. Prosecution of these claims to enforce our rights against others would involve substantial litigation expenses and divert substantial employee resources from our business. If we fail to effectively enforce our proprietary rights against others, our business will be harmed, which may cause our stock price to decline.

If the efforts of our partner, GSK, to protect the proprietary nature of the intellectual property related to the assets in the LABA collaboration, including FF/VI and UMEC/VI, are not adequate, the future commercialization of any medicines resulting from the LABA collaboration could be delayed or prevented, which would materially harm our business and could cause the price of our securities to fall.

The risks identified in the two preceding risk factors also apply to the intellectual property protection efforts of our partner, GSK. To the extent the intellectual property protection of any of the assets in the LABA collaboration are successfully challenged or encounter problems with the United States Patent and Trademark Office or other comparable agencies throughout the world, the future commercialization of these potential medicines could be delayed or prevented. Any challenge to the intellectual property protection of a late-stage development asset arising from the LABA collaboration could harm our business and cause the price of our securities to fall.

Product liability lawsuits could divert our resources, result in substantial liabilities and reduce the commercial potential of our medicines.

The risk that we may be sued on product liability claims is inherent in the development and commercialization of pharmaceutical products. Side effects of, or manufacturing defects in, products that we or our partners develop or commercialize could result in the deterioration of a patient's condition, injury or even death. Once a product is approved for sale and commercialized, the likelihood of product liability lawsuits tends to increase. Claims may be brought by individuals seeking relief for themselves or by individuals or groups seeking to represent a class. These lawsuits may divert our management from pursuing our business strategy and may be costly to defend. In addition, if we are held liable in any of these lawsuits, we may incur substantial liabilities and may be forced to limit or forgo further commercialization of the applicable products.

Although we maintain general liability and product liability insurance, this insurance may not fully cover potential liabilities. In addition, inability to obtain or maintain sufficient insurance coverage at an acceptable cost or to otherwise protect against potential product liability claims could prevent or inhibit the commercial production and sale of our products, which could adversely affect our business. Product liability claims could also harm our reputation, which may adversely affect our and our partners' ability to commercialize our products successfully, which could cause the price of our securities to fall.

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Government restrictions on pricing and reimbursement, as well as other healthcare payor cost-containment initiatives, may negatively impact our ability to generate revenues.

The continuing efforts of the government, insurance companies, managed care organizations and other payors of health care costs to contain or reduce costs of health care may adversely affect one or more of the following:

- our or our collaborators' ability to set a price we believe is fair for our products, if approved;
- our ability to generate revenues and achieve profitability; and
- the availability of capital.

The Patient Protection and Affordable Care Act and other potential legislative or regulatory action regarding healthcare and insurance matters, along with the trend toward managed healthcare in the United States, could influence the purchase of healthcare products and reduce demand and prices for our products, if approved. This could harm our or our collaborators' ability to market our potential medicines and generate revenues. Cost containment measures that health care payors and providers are instituting and the effect of the Patient Protection and Affordable Care Act and further agency regulations that are likely to emerge in connection with the passage of this act could significantly reduce potential revenues from the sale of any product candidates approved in the future. In addition, in certain foreign markets, the pricing of prescription drugs is subject to government control and reimbursement may in some cases be unavailable. We believe that pricing pressures at the state and federal level, as well as internationally, will continue and may increase, which may make it difficult for us to sell our potential medicines that may be approved in the future at a price acceptable to us or our collaborators, which may cause our stock price to decline.

If we use hazardous and biological materials in a manner that causes injury or violates applicable law, we may be liable for damages.

Our research and development activities involve the controlled use of potentially hazardous substances, including chemical, biological and radioactive materials. In addition, our operations produce hazardous waste products. Federal, state and local laws and regulations govern the use, manufacture, storage, handling and disposal of hazardous materials. We may incur significant additional costs to comply with these and other applicable laws in the future. Also, even if we are in compliance with applicable laws, we cannot completely eliminate the risk of contamination or injury resulting from hazardous materials and we may incur liability as a result of any such contamination or injury. In the event of an accident, we could be held liable for damages or penalized with fines, and the liability could exceed our resources. We do not have any insurance for liabilities arising from hazardous materials. Compliance with applicable environmental laws and regulations is expensive, and current or future environmental regulations may impair our research, development and production efforts, which could harm our business, which could cause the price of our securities to fall.

Risks Related to Ownership of our Common Stock

The price of our securities has been extremely volatile and may continue to be so, and purchasers of our securities could incur substantial losses.

The price of our securities has been extremely volatile and may continue to be so. The stock market in general and the market for biotechnology and biopharmaceutical companies in particular have experienced extreme volatility that has often been unrelated to the companies' operating performance, in particular during the last several years. The following factors, in addition to the other risk factors described in this section, may also have a significant impact on the market price of our securities:

- any adverse developments or results or perceived adverse developments or results with respect to the development of FF/VI with GSK, including, without limitation, any difficulties or delays encountered with regard to the regulatory path for FF/VI or any indication from clinical or non-clinical studies, including the large Phase 3b program, that FF/VI is not safe or efficacious (for example, the negative investor reaction to the topline results from the Phase 3 registrational programs for FF/VI announced in early 2012);

- any adverse developments or results or perceived adverse developments or results with respect to the development of UMEC/VI with GSK, including, without limitation, any difficulties or delays encountered with regard to the regulatory path for UMEC/VI, or any indication from clinical or non-clinical studies that UMEC/VI is not safe or efficacious;

- any adverse developments or results or perceived adverse developments or results with respect to the MABA program with GSK, including, without limitation, any difficulties or delays encountered with regard to the regulatory path for ‘081 or any indication from non-clinical studies of ‘081 that the compound is not safe or efficacious;

- any further adverse developments with respect to the commercialization of VIBATIV®, including, without limitation, the uncertainties surrounding drug product manufacture and supply, difficulties that may be encountered by Hospira in technology transfer activities, and how, when and where VIBATIV® will be commercialized;

- any further adverse developments or perceived adverse developments with respect to our telavancin NP NDA, which the FDA has determined cannot be approved without data from additional clinical studies, including, without limitation, any announcements made or comments emanating from the FDA’s Anti-Infective Drugs Advisory Committee meeting in November 2012;

- any adverse developments or perceived adverse developments in the field of LABAs, including any change in FDA policy or guidance (such as the pronouncement in February 2010 warning that LABAs should not be used alone in the treatment of asthma and related labeling requirements, the impact of the March 2010 FDA Advisory Committee discussing LABA clinical trial design to evaluate serious asthma outcomes or the FDA’s April 2011 announcement that manufacturers of currently marketed LABAs conduct additional clinical studies comparing the addition of LABAs to inhaled corticosteroids versus inhaled corticosteroids alone);

- GSK’s decisions whether or not to purchase, on a quarterly basis, sufficient shares of our common stock to maintain its ownership percentage taking into account our preceding quarter’s option exercise and equity vesting activity;

- any announcements of developments with, or comments by, the FDA or other regulatory authorities with respect to products we or our partners have under development or have commercialized, such as the cGMP compliance issues that the single-source VIBATIV® drug product supplier is facing with U.S. and foreign regulatory authorities;

- our incurrence of expenses in any particular quarter that are different than market expectations;

- the extent to which GSK advances (or does not advance) FF/VI, UMEC/VI and the MABA program through development into commercialization in all indications in all major markets;

- any adverse developments or perceived adverse developments with respect to our relationship with GSK, including, without limitation, disagreements that may arise between us and GSK;

- any adverse developments or perceived adverse developments with respect to our relationship with any of our research, development or commercialization partners other than GSK, including, without limitation, disagreements that may arise between us and any of those partners;

- any adverse developments or perceived adverse developments with respect to our partnering efforts with VIBATIV®, our 5-HT_4, Peripheral Mu Opioid Receptor Antagonist, MARIN and ARNI programs, TD-1792 or TD-4208;

- announcements regarding GSK generally;

- announcements of patent issuances or denials, technological innovations or new commercial products by us or our competitors;

- developments concerning any collaboration we undertake with companies other than GSK;

- publicity regarding actual or potential study results or the outcome of regulatory review relating to products under development by us, our partners or our competitors;

- regulatory developments in the United States and foreign countries;

- economic and other external factors beyond our control;

- sales of stock by us or by our stockholders, including sales by certain of our employees and directors whether or not pursuant to selling plans under Rule 10b5-1 of the Securities Exchange Act of 1934;

- relative illiquidity in the public market for our common stock (our six largest stockholders other than GSK collectively owned approximately 44.5% of our outstanding capital stock as of October 24, 2012 based on our review of publicly available filings); and

- potential sales or purchases of our capital stock by GSK.

Concentration of ownership will limit your ability to influence corporate matters.

As of October 24, 2012, GSK beneficially owned approximately 26.7% of our outstanding capital stock and our directors, executive officers and investors affiliated with these individuals beneficially owned approximately 5.5% of our outstanding capital stock. Based on our review of publicly available filings as of October 24, 2012, our six largest stockholders other than GSK collectively owned approximately 44.5% of our outstanding capital stock. These stockholders could control the outcome of actions taken by us that require stockholder approval, including a transaction in which stockholders might receive a premium over the prevailing market price for their shares.

Anti-takeover provisions in our charter and bylaws, in our rights agreement and in Delaware law could prevent or delay a change in control of our company.

Provisions of our certificate of incorporation and bylaws may discourage, delay or prevent a merger or acquisition that stockholders may consider favorable, including transactions in which you might otherwise receive a premium for your shares. These provisions include:

- requiring supermajority stockholder voting to effect certain amendments to our certificate of incorporation and bylaws;
- restricting the ability of stockholders to call special meetings of stockholders;
- prohibiting stockholder action by written consent; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

In addition, our board of directors has adopted a rights agreement that may prevent or delay a change in control of us. Further, some provisions of Delaware law may also discourage, delay or prevent someone from acquiring us or merging with us.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds.

On August 3, 2012, we completed the sale of 316,334 shares of our common stock to Glaxo Group Limited, an affiliate of GSK, at a price of $28.21 per share, resulting in aggregate gross proceeds of $8.9 million before deducting transaction expenses. Neither we nor the affiliate of GSK engaged any investment advisors with respect to the sale and no underwriting discounts or commissions were paid or will be paid to any party in connection with the sale. We issued and sold the shares in reliance upon an exemption from registration pursuant to Section 4(2) of the Securities Act of 1933, as amended.

Item 6. Exhibits

(a) **Index to Exhibits**

Exhibit Number	Description	Form	Incorporated by Reference Filing Date/Period End Date
3.3	Amended and Restated Certificate of Incorporation	S-1	7/26/04
3.4	Certificate of Amendment of Restated Certificate of Incorporation	10-Q	3/31/07
3.5	Amended and Restated Bylaws (as amended by the board of directors April 25, 2007)	10-Q	9/30/08
4.1	Specimen certificate representing the common stock of the registrant	10-K	12/31/06
4.2	Amended and Restated Rights Agreement between the registrant and The Bank of New York, as Rights Agent, dated as of June 22, 2007	10-Q	6/30/07
4.3	Indenture dated as of January 23, 2008 by and between the registrant and The Bank of New York Trust Company, N.A., as trustee	8-K	1/23/08
4.4	Form of 3.0% Convertible Subordinated Note Due 2015 (included in Exhibit 4.3)		
4.5	Amendment to Amended and Restated Rights Agreement between the registrant and The Bank of New York Mellon Corporation, as Rights Agent, dated November 21, 2008	8-K	11/25/08
31.1	Certification of Chief Executive Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated pursuant to the Securities Exchange Act of 1934, as amended		
31.2	Certification of Chief Financial Officer pursuant to Rules 13a-14(a) and 15d-14(a) promulgated pursuant to the Securities Exchange Act of 1934, as amended		
32	Certifications Pursuant to 18 U.S.C. Section 1350		

101*	The following from the registrant's Quarterly Report on Form 10-Q for the period ended September 30, 2012, formatted in Extensible Business Reporting Language (XBRL) includes: (i) the Condensed Consolidated Statements of Operations for the three and nine months ended September 30, 2012 and 2011, (ii) the Condensed Consolidated Balance Sheets as of September 30, 2012 and December 31, 2011, (iii) the Condensed Consolidated Statements of Cash Flows for the nine months ended September 30, 2012 and 2011, (iv) the Condensed Consolidated Statements of Comprehensive Income (Loss) for the three and nine months ended September 30, 2012 and 2011, and (v) Notes to Condensed Consolidated Financial Statements.

* XBRL information is furnished and not filed or a part of a registration statement or prospectus for purposes of sections 11 or 12 of the Securities Exchange Act of 1933, as amended, is deemed not filed for purposes of section 18 of the Securities Exchange Act of 1934, as amended, and otherwise is not subject to liability under these sections.

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SIGNATURES

Pursuant to the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

Theravance, Inc.
(Registrant)

October 31, 2012	/s/ Rick E Winningham
Date	Rick E Winningham Chief Executive Officer
October 31, 2012	/s/ Michael W. Aguiar
Date	Michael W. Aguiar Senior Vice President, Finance and Chief Financial Officer

Exhibit 31.1

Certification of Chief Executive Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Rick E Winningham, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Theravance, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15(d)-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

October 31, 2012
(Date)

/s/ Rick E Winningham
Rick E Winningham
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

Certification of Chief Financial Officer
Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Michael W. Aguiar, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Theravance Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15(d)-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

October 31, 2012
(Date)

/s/ Michael W. Aguiar
Michael W. Aguiar
Senior Vice President, Finance and
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32

CERTIFICATION OF CHIEF EXECUTIVE OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Rick E Winningham, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of Theravance Inc. on Form 10-Q for the three months ended September 30, 2012 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended and that information contained in such Quarterly Report on Form 10-Q fairly presents in all material respects the financial condition of Theravance, Inc. at the end of the periods covered by such Quarterly Report on Form 10-Q and results of operations of Theravance, Inc. for the periods covered by such Quarterly Report on Form 10-Q.

October 31, 2012 By: /s/ Rick E Winningham
(Date) **Name: Rick E Winningham**
Title: Chief Executive Officer

CERTIFICATION OF CHIEF FINANCIAL OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

I, Michael W. Aguiar, certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that the Quarterly Report of Theravance Inc. on Form 10-Q for the three months ended September 30, 2012 fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended and that information contained in such Quarterly Report on Form 10-Q fairly presents in all material respects the financial condition of Theravance, Inc. at the end of the periods covered by such Quarterly Report on Form 10-Q and results of operations of Theravance, Inc. for the periods covered by such Quarterly Report on Form 10-Q.

October 31, 2012 By: /s/ Michael W. Aguiar
(Date) **Name: Michael W. Aguiar**
Title: Senior Vice President, Finance and Chief Financial Officer